Panel Discussion
FDA and Industry Collaboration on Computer Software Assurance (CSA)
20th Annual Computer And IT Systems Validation, April 23, 2019

Panelists:
➢ Khaled Moussally, Compliance Group – Global Head of QMS
➢ Jason Spiegler, Siemens Digital Industries Software – Senior Director, Strategic Initiatives & Customers, Life Sciences Practice
➢ Kurt Weber, Vericel Corporation - Director of Information Technology
➢ Harsha Chulki, ICU Medical - Head of Global IT Quality & CSV
➢ Ken Shitamoto, Gilead Sciences – Sr Director, IT

Material Contributors:
➢ Cisco Vicentey, Office of Compliance, FDA (CDRH)
Objectives:

➢ Create awareness to accelerate innovation
➢ Inspire action so you can begin to realize value

Agenda:

➢ Quick recap on FDA CSV Team’s journey and CSA Draft Guidance
➢ Panel discussion on:
  o Recent recommendations to the Draft Guidance
  o Success Stories: Vericel, Gilead Sciences and ICU Medical
  o “Test More; Document Less”
➢ Q&A and Open Discussion

“Computer Software Assurance for Manufacturing, Operations, and Quality System Software”
Computer System Validation!

What do you love about it?

What do you dislike about it?
What’s the background?
FDA Case for Quality begins

2011 - 2012

2015
Q2

Siemens – Fresenius
Executive Exchange w/ FDA:
CSV Barrier identified

Industry team formed / recommendation development begins

2016
Q1

Begin promoting recommendations:
Zoll Lifevest + Medtronic value examples

2017

• FDA “A List” status for CSA Draft Guidance
• More examples developed
• More firms applying recommendations (Vericel, ICU Medical, Gilead, etc)

2018

2019

• More industry adoption
• CSA Draft Guidance release targeted for 2019

www.fda.gov
CSV identified as a barrier for the FDA...

Leveraging Technology To Realize Value From A Global Dynamic Manufacturing Operating Model
June 3, 2015

For your technology investments, what are the barriers for Realizing Value?

CSV!!!
The Industry CSV Team

<table>
<thead>
<tr>
<th>Company</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare</td>
<td>Tina Koepke</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Damien McPhillips</td>
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<td>Boston Scientific</td>
<td>Ray Murphy</td>
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<tr>
<td>Compliance Group</td>
<td>Khaled Moussally</td>
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<td>Edwards Lifesciences</td>
<td>Penny Sangkhavichith</td>
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<td>Edwards Lifesciences</td>
<td>Andy Lee</td>
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<td>FDA</td>
<td>Cisco Vicenty</td>
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<td>FDA</td>
<td>John Murray</td>
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<td>Fresenius Medical Care</td>
<td>Bill D’Innocenzo</td>
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<td>Fresenius Medical Care</td>
<td>Curt Curtis</td>
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<td>Fresenius Medical Care</td>
<td>Marc Koetter</td>
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<td>Johnson and Johnson</td>
<td>Dana Guarnaccia</td>
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<td>Johnson and Johnson</td>
<td>Ron Schardong</td>
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<td>Lanthmus Imaging</td>
<td>Lou Poirier</td>
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<td>Medtronic</td>
<td>Frankie Bill</td>
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<td>Medtronic</td>
<td>Michael Branch</td>
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<td>Medtronic</td>
<td>April Francis</td>
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<td>NeuroVision Imaging</td>
<td>Pepe Davis</td>
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<td>Ortho-Clinical Diagnostics</td>
<td>Des Chesterfield</td>
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<tr>
<td>Siemens PLM</td>
<td>Jason Spiegler</td>
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<td>Siemens PLM</td>
<td>Greg Robino</td>
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<td>Siemens PLM</td>
<td>Thorsten Ruehl</td>
</tr>
<tr>
<td>Zoll Lifevest</td>
<td>Frank Meledandri Sr.</td>
</tr>
</tbody>
</table>

Contributions also provided by past team members:
Stacey Allen, Jason Aurich, Sean Benedik, Laura Clayton, Bill Hargrave, Joe Hens, Scott Moeller & Mark Willis
Non-Product CSV is foundational ... 

for enabling the “Digital Thread” of Smart Manufacturing
What are the pain points in CSV?
Common CSV Pain points

- Takes forever
- Too much focus on document generation
- Perceived Regulatory burden - doing things for the auditor
- Test Scripts that often run into tens of pages
- Test Script errors & costly defect management
- Paper based processes
- Complex, hard to use Risk-based approaches
Quick recap of FDA – Industry CSV Team’s recommendations and what’s new?
Key Take Aways

Why Now?
Med Dev lags other industries
• Lack of clarity
• Outdated compliance approach
• Perceived regulatory burden
• Reduces manufacturer’s capability to learn, react, & improve
Key Take Aways

Why Now?

Create a Paradigm Shift...
• Streamline with value-driven, patient focused approaches
• Critical thinking & risk-based agile approaches
• Improve manufacturer’s capabilities with automation

Defining Risk
• Clearly define “intended use”.
• Focus on the “direct impact on device safety and device quality”, and does it result in “patient/user safety risk?” See examples.
  ➢ LMS vs Manufacturing Equipment Software
• For PMA Products, CDRH is exploring using risk determination to make implementation of systems an annually reportable change no 30-Day Notice

Risk Based Assurance Strategies
• Take credit for work already done
  ➢ Leverage existing activities and trusted supplier data
• Use Agile test methods (e.g. unscripted testing) when appropriate
• Mitigate risk with downstream process controls
• Leverage continuous data and information for monitoring and assurance

Assurance Evidence Capture
• Use CSV tools to automate assurance activities
  Note: FDA does not intend to review validation of support tools.
• Use electronic data capture & record creation vs paper documentation, screen shots, etc.
## Acceptable record of results

<table>
<thead>
<tr>
<th>Assurance Approach</th>
<th>Test Plan</th>
<th>Test Results</th>
<th>Record (Digital Acceptable)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unscripted Testing:</strong> Ad-hoc (with least-burdensome documentation)</td>
<td>• Testing of features and functions with no test plan</td>
<td>• Details regarding any failures/deviations found</td>
<td>• Summary description of features and functions tested&lt;br&gt;• Issues found and disposition&lt;br&gt;• Conclusion statement&lt;br&gt;• Record of who performed testing and date</td>
</tr>
<tr>
<td><strong>Unscripted Testing:</strong> Error guessing</td>
<td>• Testing of feature and function fail-modes with no test plan</td>
<td>• Details regarding any failures/deviations found</td>
<td>• Summary description of fail-modes tested&lt;br&gt;• Issues found and disposition&lt;br&gt;• Conclusion statement&lt;br&gt;• Record of who performed testing and date</td>
</tr>
<tr>
<td><strong>Unscripted Testing:</strong> Exploratory Testing</td>
<td>• Establish high level test plan objectives for features and functions (no step-by-step procedure is necessary)</td>
<td>• Pass/fail for each test plan objective&lt;br&gt;• Details regarding any failures/deviations found</td>
<td>• Summary description of features and functions tested&lt;br&gt;• Result for each test plan objective – only indication of pass/fail&lt;br&gt;• Issues found and disposition&lt;br&gt;• Conclusion statement&lt;br&gt;• Record of who performed testing and date</td>
</tr>
<tr>
<td><strong>Scripted Testing:</strong> Limited</td>
<td>• Limited Test cases (step-by-step procedure) identified&lt;br&gt;• Expected results for the test cases&lt;br&gt;• Identify unscripted testing applied&lt;br&gt;• Independent review and approval of test plan.</td>
<td>• Pass/fail for test case identified&lt;br&gt;• Details regarding any failures/deviations found and disposition regarding fails</td>
<td>• Summary description of features and functions tested&lt;br&gt;• Result for each test case - only indication of pass/fail&lt;br&gt;• Issues found and disposition&lt;br&gt;• Conclusion statement&lt;br&gt;• Record of who performed testing and date&lt;br&gt;• Signature and date of appropriate signatory authority</td>
</tr>
<tr>
<td><strong>Scripted Testing:</strong> Robust</td>
<td>• Test objectives&lt;br&gt;• Test cases (step-by-step procedure) &lt;br&gt;• Expected results&lt;br&gt;• Independent review and approval of test cases.</td>
<td>• Pass/fail for test case&lt;br&gt;• Details regarding any failures/deviations found and disposition regarding fails</td>
<td>• Detailed report of assurance activity&lt;br&gt;• Result for each test case - only indication of pass/fail&lt;br&gt;• Issues found and disposition&lt;br&gt;• Conclusion statement&lt;br&gt;• Record of who performed testing and date&lt;br&gt;• Signature and date of appropriate signatory authority</td>
</tr>
</tbody>
</table>
Spreadsheet to Analyze and Graph Non-conformances

The manufacturer developed a spreadsheet used to analyze, and graph non-conformances stored in a controlled system. Intended use of the spreadsheet is found to have a low patient risk.

- **Intended Use**: Analyze and graph non-conformances data stored in a controlled system
- **Risk Assessment**: The intended use of the spreadsheet is for analyzing process quality outcomes and is identified as a high-risk function. The manufacturing process includes additional changes and inspections that assure non-conformances do not escape therefore the patient risk is low.
- **Tested**: Spreadsheet X, Version 1.2
- **Test type**: Unscripted testing – exploratory testing
- **Goal**: Ensure that analyses can be Created/Read/Updated/Deleted
- **When/Who**: July 9, 2019, by John Smith
- **Testing activities**: Created, updated, and deleted analyses and observed that all calculated fields were correctly updated
- **Conclusion**: No errors observed

That’s it!
No more documentation required!
### Complaint Handling Spreadsheet example

<table>
<thead>
<tr>
<th>Patient/Quality System Risk</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Errors in the spreadsheet outputs will cause death, life-threatening harm or irreversible damage to patient and/or fail the direct implementation of a quality system activity defined in a regulation.</td>
</tr>
</tbody>
</table>
|                            | • Manufacturing equipment controls  
|                            | • Automated product inspection  
|                            | • Label management & automation  
|                            | • QC Laboratory test calculations  
|                            | • Adverse event tracking  
|                            | • Clinical trial results  
| **Medium**                 | Errors in the spreadsheet outputs will cause significant but temporary harm or reversible damage to patient and/or fail to support the indirect implementation of a quality system activity defined in a regulation. |
|                            | • Product Complaint Tracking  
|                            | • Product quality status management  
|                            | • Product Complaints Trending  
|                            | • Spreadsheet supporting managers review the training assigned to either to their employees (the system that directly implements the quality system activity is the Learning Management System)  
| **Low**                    | Errors in the spreadsheet outputs will cause minor harm to a patient and/or fail to implement a quality system activity not defined in a regulation. |
|                            | • Company specific quality trending spreadsheets not required by regulation.  
| **None**                   | No direct or indirect impact on patient |
|                            | • Manufacturing cost reports  
|                            | • Turnaround time reports  
|                            | • Project Management tools  
|                            | • Task tracking, Schedule  
|                            | • Activity Due Date Calculator (Non-Product)  
|                            | • Vendor Assessment Checklist  

<table>
<thead>
<tr>
<th>Implementation Method</th>
<th>Out of The Box</th>
<th>Configured</th>
<th>Custom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Unscripted Testing</td>
<td>Limited Scripted Testing</td>
<td>Robust Scripted Testing</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Ad-Hoc Testing (With Record)</td>
<td>Unscripted Testing</td>
<td>Limited Scripted Testing</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Ad-Hoc Testing (With Record)</td>
<td>Ad-Hoc Testing (With Record)</td>
<td>Unscripted Testing</td>
</tr>
</tbody>
</table>

### Implementation Method Examples for Spreadsheets

- **Out of the Box**: Printing functions, Formatting functions, Simple Arithmetic Operations (e.g. sum, average, std.dev), Simple Cell Relationships and Range Operations
- **Configured**: Formulae (including statistical functions), Single level Boolean functions (If, And, Or), Charts, Conditional Statements, Nested Functions, Security (Cell Protection), Pivot tables
- **Custom**: Custom Macros, VBA Code, Extensive Nested Logic Functions (e.g. IF(condition1, value_if_true1, IF(condition2, value_if_true2, IF(condition3, value_if_true3, value_if_false3)))

### Patient/Quality System Risk Examples

- **High**: Errors in the spreadsheet outputs will cause death, life-threatening harm or irreversible damage to patient and/or fail the direct implementation of a quality system activity defined in a regulation. Examples include:
  - Manufacturing equipment controls
  - Automated product inspection
  - Label management & automation
  - QC Laboratory test calculations
  - Adverse event tracking
  - Clinical trial results

- **Medium**: Errors in the spreadsheet outputs will cause significant but temporary harm or reversible damage to patient and/or fail to support the indirect implementation of a quality system activity defined in a regulation. Examples include:
  - Product Complaint Tracking
  - Product quality status management
  - Product Complaints Trending
  - Spreadsheet supporting managers review the training assigned to either to their employees (the system that directly implements the quality system activity is the Learning Management System)

- **Low**: Errors in the spreadsheet outputs will cause minor harm to a patient and/or fail to implement a quality system activity not defined in a regulation. Examples include:
  - Company specific quality trending spreadsheets not required by regulation.

- **None**: No direct or indirect impact on patient. Examples include:
  - Manufacturing cost reports
  - Turnaround time reports
  - Project Management tools
  - Task tracking, Schedule
  - Activity Due Date Calculator (Non-Product)
  - Vendor Assessment Checklist

### Spreadsheet Description / Intended Use

<table>
<thead>
<tr>
<th>Patient/Quality System Risk Level</th>
<th>Implementation Method</th>
<th>Assurance Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Custom</td>
<td>Robust Scripted Testing</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Custom (VBA Macros)</td>
<td>Limited scripted testing</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Configured</td>
<td>Ad-hoc testing</td>
</tr>
<tr>
<td><strong>None</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Product Recall Decision Matrix
- Assessed form used to decide the “recall” status of a product based on predefined trending criteria.

### Complaint Trending Tool
- Extract complaint data from various sources and identify complaint trends.

### Non-conformance data analysis
- Analyze and graph non-conformances data stored in a controlled system.

### Examples of Implementation Methods for Spreadsheets

- **Out of the Box**: Simple functions like sum, average, std.dev, and simple cell relationships and range operations.
- **Configured**: Advanced functions such as formulae, conditional statements, nested functions, security, and pivot tables.
- **Custom**: Custom code, VBA, and extensive nested logic functions.
Qualification of Automated CSV Tools

These intended uses of these tools are not part of production or the quality system, therefore should not be considered within the requirements of 21 CFR 820.70(i).

Examples include:

- Code Debugger (for CAPA Automation use case)
- Loadrunner (for simulating anticipated peak load of ERP production system use case)
- Defect management and ALM tools

Assurance Process

Step 1: Identify where and how tool will be used within your organization
Step 2: Determine if the Off the Shelf tool is part of, integrated, or used for automating production or Quality Management
Step 3: Assure the use within your organization
Step 4: Capture Evidence
Can you provide examples of applying these recommendations and the resulting value?
**Vericel Industry Case Study – Unscripted Testing**

**Standard Scripted Testing Approach**

- **20%** Test
- **80%** Document
- **80%** Production Scheduling system (much smaller than ERP) took much longer
- **80%** issues were test script issues
- Focus on documentation, not on testing
- High validation spend & time

**FDA – Industry Streamlined Approach**

- **80%** Test
- **20%** Document
- ERP System validated in 3 months
- Approach leveraged for EBR system
- 90% reduction in test script issues
- > 50% reduction in validation spend & time
Vericel Industry Case Study – Risk Framework

Legacy Risk Assessment Framework

80% Focus on Testing
20% Focus on Documentation

% Time Spent

Legacy Risk Framework Worksheet

New FDA CSV Risk Framework

80% Focus on Testing
20% Focus on Documentation

% Time Spent

FDA CSV Risk Framework Worksheet

<table>
<thead>
<tr>
<th>Req/Spec ID(s)</th>
<th>Patient Risk</th>
<th>Risk Rating</th>
<th>Mitigation Strategy</th>
<th>Test Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spec ID #1</td>
<td>High</td>
<td>5</td>
<td>Required Mitigation 1</td>
<td>Scripted Testing</td>
</tr>
<tr>
<td>Spec ID #2</td>
<td>Medium</td>
<td>3</td>
<td>Required Mitigation 2</td>
<td>Unscripted Testing – Error Guessing</td>
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<tr>
<td>Spec ID #3</td>
<td>Low</td>
<td>2</td>
<td>N/A</td>
<td>Unscripted Testing – Exploratory Testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requirement/Specification</th>
<th>Risk Assessment</th>
<th>Test Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Req/Spec ID</td>
<td>Req/Spec</td>
<td></td>
</tr>
<tr>
<td>Gap Relevance</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>GoP Failure Consequence</td>
<td>Major</td>
<td></td>
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<tr>
<td>Business Failure Consequence</td>
<td>High</td>
<td></td>
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<tr>
<td>Quality of Failure Consequence</td>
<td>Required Mitigation 1</td>
<td>Challenge Test</td>
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<tr>
<td>Mitigation Strategy</td>
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<tr>
<td>Final Test Strategy</td>
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<td>Test Strategy Verification</td>
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<td>Additional Verifications</td>
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</tr>
<tr>
<td>Comments (optional)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Spec ID #1: Specification description 1
Spec ID #2: Specification description 2
Spec ID #3: Specification description 3
ICU Industry Case Study – Unscripted Testing

Legacy Approach

+ Time for drafting and executing: 2X
+ More Test Script & Tester errors: 95%
+ Less system issues found: 50%

FDA CSV Team Approach

+ Reduction in validation testing cycle times: 75%
+ Reduction in Test Script & Tester errors: 95%
+ Reduction in Validation Testing spend: 60%
Gilead Empirical Analysis

Retrospective Validation Effort Comparison of Traditional vs. New Model

<table>
<thead>
<tr>
<th>System Name</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Change Management System* (Jan 2014)</td>
<td></td>
</tr>
<tr>
<td>Electronic Document Management System (Dec 2014)</td>
<td></td>
</tr>
<tr>
<td>Laboratory Execution System (May 2015)</td>
<td></td>
</tr>
<tr>
<td>Process Control System* (May 2016)</td>
<td></td>
</tr>
<tr>
<td>Environmental Monitoring System (Jul 2016)</td>
<td></td>
</tr>
<tr>
<td>Product Serialization System (Aug 2018)</td>
<td></td>
</tr>
</tbody>
</table>

* Bold = favorable audit
How have these Recommendations been received by the auditors/investigators?
“………….sitting here with “EU Notified Body” auditor for our 13485-2016 audit.. just talked software application validation for the last hour. Our auditor was impressed with everything we have set up, loved the risk based approach. Told us that other companies get into lots of arguments with him over this and it was refreshing to talk with us. He personally likes defined OQ verbiage, however how I explained we do our test cases in test and live environments and he agreed it was just a wording thing on his part. We also talked a lot about the difference between verification activities vs validation activities and effectively setting up test cases. He was impressed with everything we had...................”

“........................It was awesome finally going through a validation and being assured that things were good from the EU perspective as well...

- Frank M.
What are your next steps?
How are you planning to automate?
Next Steps

- Continue developing Use Cases and new recommendations

- Encourage manufacturers to start using recommendations
  - Capture value - measure better, faster, and less expensive CSV activity and…
  - Provide FDA with input on what is working vs not working, barriers, etc

- FDA 2019 “A List” - new Non-Product CSV FDA Guidance to encourage automation and clarify expectations for risk-based CSV.
  
  Your assignment: Provide comments to the Docket!

- Review and possibly modify 820.70(i) – improve clarity on automated processes

- Promoting recommendations through recorded Webinar:
For Questions

Contact:
Khaled Moussally (khaled@compliance-g.com)
Jason Spiegler (Jason.spiegler@siemens.com)
Cisco Vicent (Francisco.Vicent@fda.hhs.gov)
BONUS MATERIAL
FDA’s View of Automation

The FDA supports and encourages the use of automation, information technology, and data solutions throughout the product lifecycle in the design, manufacturing, service, and support of medical devices. Automated systems provide manufacturers advantages for reducing or eliminating errors, increasing business value, optimizing resources, and reducing patient risk. Is based on learning from other industries where automation has already shown significant benefits in enhancing product quality and safety, which in turn reduces Risk, compared with non-automation.

www.fda.gov
Draft Guidance Topics

- Content of Premarket Submissions for Cybersecurity of Medical Devices of Moderate and Major Level of Concern
- Surgical Staplers and Staples – Labeling Recommendations
- Non-binding Feedback After Certain FDA Inspections of Device Establishments
- Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices
- Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies
- **Computer Software Assurance for Manufacturing, Operations, and Quality System Software**
- Patient Engagement in Clinical Trials
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Lifecycle Regulatory Requirements of Medical Device Servicing (Device Servicer vs Remanufacturer)
- Guidance on an Accreditation Scheme for Conformity Assessment of Medical Devices to FDA-Recognized Consensus Standards (ASCA).

FDA announcement link. [https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm529396.htm](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm529396.htm)
Scope of the Guidance

Scope

- Manufactures, including combination product manufactures, who have established a 21 CFR 820 quality system.

Out of Scope

- Automation of Clinical Trial and associated Electronic Records
- Automation regulated outside of 21 CFR 820
- Software validation for devices under the requirements of 21 CFR 820.30(g).
- Information Technology Infrastructure assurance activities such as planning, contracting, or continuity of operations efforts that are used to maintain server operations.
Focus on Assurance

Shift the discussion
### Intended Use
- What is the intended use?
- Does feature, operation, or function directly impact:
  - device safety
  - device quality or
  - quality system integrity?

### Risk Based Approaches
- Do automation features, operations, or functions directly impact device safety or device quality?
  - High-risk areas may require the most rigorous assurance effort to ensure they perform as intended.
- FDA intends focus on areas that **Directly** impact device safety or device quality. FDA does not intend to focus on **Indirect** impact areas. Ex: MES or LIMS compared with an LMS.

### Assurance (Testing) Approaches
- Provide confidence that the system, feature, or function performs as expected and meets intended use.
- Assurance Activities driven by the Risk associated with the system, feature, or function, depending on how you approach it (e.g. Direct vs Indirect).
- Traditional IQ/OQ/PQ is not necessary for CSV.
- Next slides will include examples of assurance activities, including numerous Agile testing methods.

### Evidence Capture Methods
- Least-burdensome record (see next slides). Record needs to be of value to the Manufacturer, not the Investigator or Auditor.
- CSV tools encouraged to automate assurance activity. **Use electronic data capture and record creation** (vs paper documentation, screen shots, etc).
  - 21 CFR 820.70(i) is applied only when software part of production or quality system. FDA does **Not Intend** to review validation of support tools. Manufacturer responsible for determining assurance.
  - Part 11 narrowly scoped & under enforcement discretion (**apply appropriately**).
What does FDA care about? Risk Considerations

- Direct impact to device quality and device safety that also has a direct patient safety risk
  - Directly impacts physical properties of the product or manufacturing process identified as essential to device safety or device quality by the manufacturer
  - Measures, inspects, analyzes, and or dispositions the product or process
  - Determines acceptability or performs process corrections without human intervention, awareness, or review
  - Directly impacts labeling, instructions for use, or direct alerts or communications to the user
  - Automates surveillance, trending, or tracking of product quality or patient safety issues identified as essential by the manufacturer
Appropriate methods and activities for software assurance

- Take a least-burdensome approach – focus on value for the Manufacturer, not the Investigator.
- Leverage existing activities and supplier data. Do not reinvent the wheel; take credit for work already done.
- Leverage use of process controls to mitigate risk.
- Use Computer System Validation tools to automate assurance activities.
  - Scope of 21 CFR 820.70(i) is applied when computers or automated data processing systems are used as part of production or quality system.
  - FDA does not intend to review validation of support tools. Manufacturer determines assurance activity of these tools for their intended use.
  - Part 11 narrowly scoped and is under enforcement discretion apply appropriately.
- Use Agile testing methods and unscripted testing as appropriate.
- Use electronic data capture and record creation, as opposed to paper documentation, screen shots, etc.
- Leverage continuous data and information for monitoring and assurance.
Examples
FDA CSV Team Recommendations – Case Study Themes

- Embrace Automation
  - Implement consistent risk frameworks
  - Adopt patient centric approaches

- Follow Risk-based Assurance
  - Scale the level of documentation

- Embrace Automation
  - Automation needs to be seen as an enabler.
  - Automation doesn’t need to involve complex tools.
Non Product CSV Success Story: Value of FDA Collaboration

A Paradigm Shift – The Impact

<table>
<thead>
<tr>
<th>Metric</th>
<th>Pre</th>
<th>Post</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation System Change Backlog (Camstar &amp; Epicor)</td>
<td>• 90 changes in backlog</td>
<td>• 0 Changes in backlog</td>
<td>• High morale</td>
</tr>
<tr>
<td></td>
<td>• Extreme Frustration</td>
<td></td>
<td>• More value from systems</td>
</tr>
<tr>
<td></td>
<td>• Low morale</td>
<td></td>
<td>• Higher quality/productivity</td>
</tr>
<tr>
<td>CSV Time per Test Case</td>
<td>• 30.7 Labor Hours Avg</td>
<td>• 11.2 Labor Hours Avg</td>
<td>• 64% Labor Hour reduction</td>
</tr>
<tr>
<td>Camstar (MES) System SU 13 Upgrade Validation</td>
<td>• 1,044 Labor Hours</td>
<td>• 381 Labor Hours</td>
<td>• 633 Labor Hour Reduction</td>
</tr>
<tr>
<td></td>
<td>• 5 Head Count</td>
<td>• 2 Head Count</td>
<td>• 3 Head Count Reduction</td>
</tr>
<tr>
<td>CSV Turnaround Time: Days from change submitted until Test Case Completed</td>
<td>• 29.5 Days per CSV</td>
<td>• 1.5 Days per CSV</td>
<td>• 95% Reduction CSV Turnaround</td>
</tr>
<tr>
<td>Process Validation Time</td>
<td>38 day Average</td>
<td>7 day Average</td>
<td>• 83% reduction</td>
</tr>
<tr>
<td>Service Defect Tracking (Camstar customization)</td>
<td>PQ = 22 runs, 35 days</td>
<td>PQ = 1 run, 3 days</td>
<td>• 91% reduction</td>
</tr>
<tr>
<td>Camstar SU13 Upgrade Project Start</td>
<td>• Projected - Feb ‘18</td>
<td>• Actual - Nov ‘17</td>
<td>• Bug Fixes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• System Performance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functionality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Increased Throughput</td>
</tr>
</tbody>
</table>

Scope:
- Camstar MES
- Epicor ERP

Best practices leveraged from the Industry Team:
- Vendor Qualification
- Unscripted / Ad-Hoc Testing
- Analytics and Reporting
- Automated CSV Risk Management
# PAVING WAY FOR A NEW QUALITY CULTURE

## RISK BASED TESTING FOR IT SOFTWARE

**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 LOW
- Standard traceability Requirements to Test cases
- Informal testing for IT system
- Informal testing for UAT

### Change Level Risk MEDIUM
- Standard traceability Requirements to Test cases
- Formal testing of all new requirement for IT system testing
- Informal execution of regression testing
- Informal execution of UAT

### Change Level Risk HIGH
- Add traceability from Requirements to Design to Test case
- Test all new requirements
- Execute formal regression testing

*Presented by Medtronic on March 12, 2019 at IVT Medical Device Week in Minneapolis MN*
CSV RISK MANAGEMENT AUTOMATION
POLARION

WHAT IS IT?

An application lifecycle tool that manages software development projects

*Presented by Medtronic on March 12, 2019 at IVT Medical Device Week in Minneapolis MN
**GLOBAL IT QUALITY PAIN POINTS & SOLUTIONS**

<table>
<thead>
<tr>
<th>REPEAT ISSUES</th>
<th>POLARION SOLUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Quality deliverables</td>
<td><strong>Workflow auto-populates required quality</strong></td>
</tr>
<tr>
<td>Can’t find Quality deliverables</td>
<td>deliverables based on project type</td>
</tr>
<tr>
<td>Project resources missing RBT evidence</td>
<td><strong>Deliverables organized by system &gt;&gt; project/change</strong></td>
</tr>
<tr>
<td>Quality deliverable sequence issues</td>
<td><strong>User Access requires RBT completion</strong></td>
</tr>
<tr>
<td>Incorrect template version used</td>
<td><strong>Workflow enforces sequence</strong></td>
</tr>
<tr>
<td>Deliverables have imbedded files or links</td>
<td><strong>Auto-populates current version and highlights</strong></td>
</tr>
<tr>
<td>Incorrect or missing approvals</td>
<td><strong>delta changes if using previous approved deliverable</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Automatically removes imbedded files or links in rendering deliverable</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Auto-populates minimum required roles per deliverables type</strong></td>
</tr>
</tbody>
</table>

*Presented by Medtronic on March 12, 2019 at IVT Medical Device Week in Minneapolis MN*
### POLARION USE IN MEDTRONIC NON-PRODUCT SOFTWARE

- **Reduce CAPAs, Audits and time** needed to reconcile these issues
- **Automate** Global IT’s validation processes while **supporting** a **unified and consistent** Global IT demand process

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>USER FRIENDLY</th>
<th>IMPROVED DOCUMENTATION</th>
<th>TRACEABILITY END-TO-END</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Easy to adopt, use and support</td>
<td>Central repository for living validation documentation</td>
<td>Electronic signatures 21CFR part 11 compliant</td>
</tr>
<tr>
<td></td>
<td>Flexible process for validated and non-validated applications/projects</td>
<td>Real time template updates applied to new documents</td>
<td>System of record for validation status</td>
</tr>
<tr>
<td></td>
<td>Repeatable process execution across the Global IT organization</td>
<td>Eliminate paper execution of methodology</td>
<td>Ability to support on-demand IT audits</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Migration of existing data (documents, QC)</td>
<td>Cross-functional reporting</td>
</tr>
</tbody>
</table>

*Presented by Medtronic on March 12, 2019 at IVT Medical Device Week in Minneapolis MN*
## Case Study Examples – Embrace Automation – Infrastructure Qualification

### FDA CSV Team Recommendation

<table>
<thead>
<tr>
<th>FDA CSV Team Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Use <strong>electronic</strong> data capture and record creation, vs <strong>paper</strong> documentation, screen shots, etc.</td>
</tr>
<tr>
<td>- Leverage continuous data and information for monitoring and assurance</td>
</tr>
</tbody>
</table>

### Success Story Brief Description

<table>
<thead>
<tr>
<th>Success Story Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Replaced <strong>manual, paper based</strong> test evidence capture with an <strong>automated</strong> approach.</td>
</tr>
<tr>
<td>- Replaced <strong>manual, error-prone</strong> specification maintenance with an <strong>automated, error-free</strong> specification generation approach.</td>
</tr>
</tbody>
</table>

### Before

- **Manual** screen shots of evidence of server’s hardware and software specifications.
- Manual and **reactive** maintenance of infrastructure specifications – specifications are often not in sync with the actual infrastructure as infrastructure is so dynamic.
- Time taken – **10X**

### After

- **Automated** reports of server’s hardware and software specifications by installing monitoring tools on servers.
- Automated, **proactive** generation of infrastructure specifications with the click of a button. Continuous data monitoring and assurance.
- Time taken – **1X**
# Case Study Examples – Embrace Automation – Smart Glasses

<table>
<thead>
<tr>
<th><strong>FDA CSV Team Recommendation</strong></th>
<th><strong>Success Story Brief Description</strong></th>
</tr>
</thead>
</table>
| • Use electronic data capture and record creation, as opposed to paper documentation  
• Use Computer System Validation tools to automate assurance activities  
• FDA does not intend to review validation of support tools. Manufacturer determines assurance activity of these tools for their intended use. | • Replaced travel-intensive, hands-on training with remote, hands-free training using Smart Glasses (A wearable, voice-recognition & AI based technology)  
• Automatic, hands-free, safe evidence capture & voice-enabled real time, online documentation |

### Before

- **In person** training (with expensive travel) required per procedures in order to perform certain manufacturing tasks.

- **Hands-on** picture capture with external camera, **print out and attach** to documentation **offline**. **Error prone**.

- Deviations due to missed output recordings.

- Time taken – **5X**

---

### After

- **Remote** training using wearable, hands-free, AI powered Smart Glasses technology.

- **Hands free** evidence capture with **voice-powered real-time** documentation. **Error free**.

- No deviations due to missed recordings.

- Time taken – **1X**
### Case Study Examples – Risk based Assurance – Consistent Frameworks

<table>
<thead>
<tr>
<th>FDA CSV Team Recommendation</th>
<th>Success Story Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>• FDA is interested in the situations when a failure to fulfill the intended use of the system, software, or feature directly impacting device safety and device quality results in direct patient safety risk.</td>
<td>• Deployed a patient centric risk framework across Software life-cycle – i.e. Validation, Change Management &amp; Periodic Reviews.</td>
</tr>
<tr>
<td></td>
<td>• Leveraged FDA CSV Team’s risk assurance framework.</td>
</tr>
</tbody>
</table>

#### Before

- Siloed risk frameworks across processes – frameworks that don’t talk to each other
- Confusion among implementing teams with risk definitions that don’t align with each other
- Redundant work efforts due to misalignment

#### After

- Consistent, simplified risk framework across processes that drive a common risk based assurance approach
- Consistent implementation of harmonized risk assurance framework
- Reduced cycle times from consistent interpretations across processes
## Case Study Examples – Risk based Assurance – Deliverable Scalability

### FDA CSV Team Recommendation
- FDA is interested in the situations when a failure to fulfill the intended use of the system, software, or feature directly impacting device safety and device quality results in direct patient safety risk.

### Success Story Brief Description
- Deployed a software validation framework in which deliverables are scaled based on risk level of the software.
- Leveraged FDA CSV Team’s risk assurance framework.

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>• One-size-fits-all list of validation documentation for all types of software</td>
<td>• Deliverables scaled (both quantity &amp; quality) by using a risk assurance framework included in FDA CSV Team’s recommendations</td>
</tr>
<tr>
<td>• Creation of documentation – not assurance</td>
<td>• Creation of “assurance” – not just documentation</td>
</tr>
<tr>
<td>• Time consuming validation cycles</td>
<td>• At least 25% improvement in validation cycles</td>
</tr>
</tbody>
</table>
### Implementation Definitions

<table>
<thead>
<tr>
<th>Risk</th>
<th>Patient/Product</th>
<th>Out of the Box</th>
<th>Configured</th>
<th>Custom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Minor harm to a patient.</td>
<td>Feature works simply by installing the software and adding necessary master data.</td>
<td>Feature is enabled through the setting of parameters without changing the code.</td>
<td>Feature requires programming or change to software code.</td>
</tr>
<tr>
<td>Medium</td>
<td>Significant but temporary harm or reversible damage to a patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Death, life-threatening harm, or irreversible damage to a patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Implementation Method

<table>
<thead>
<tr>
<th>Patient Risk</th>
<th>Out of the Box</th>
<th>Configured</th>
<th>Custom</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Medium</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### Replacing custom MES with COTS MES.

**Vendor Qualification:** Mature vendor, trusted in industry, ISO certified, very transparent, robust SDLC, etc.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Patient Risk Level</th>
<th>Assurance Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training Enforcement</td>
<td>Low (Product quality inspected at multiple steps in process)</td>
<td>3 - Unscripted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - Vendor Audit</td>
</tr>
<tr>
<td>Material Expiration</td>
<td>Medium</td>
<td>4 - Limited Scripted</td>
</tr>
<tr>
<td>Enforcement</td>
<td></td>
<td>2 - Ad Hoc</td>
</tr>
<tr>
<td>Label Printing</td>
<td>High</td>
<td>5 - Scripted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 - Unscripted</td>
</tr>
</tbody>
</table>

*Out of the Box implementation*
Example: Annual Filing vs 30 Day PMA Notification

Scenario 1: COTS MES to replace paper based manufacturing / DHR

- Intended Use: MES will automate functions currently performed manually, providing 5M enforcement, data collection, track/trace, label printing, etc while removing variability and cost from their process. No customizations. Scripted testing for high risk (label printing); unscripted testing for medium and low risk features.

- COTS MES from a trusted, established vendor within the industry (ISO certified, robust SDLC, etc).

- Physical manufacturing process is not changing. Downstream controls to inspect/check product remain.

- Based on downstream controls and risk based assurance approach, device quality, device safety, and patient/user safety risk have been mitigated. CDRH may accept filing in an annual report. Note – this is developing policy evaluation.

Scenario 2: COTS MES Upgrade

- Intended use: Refer to scenario 1. No new features. Unscripted to verify no unintended issues (try to break system). No customizations. The Physical manufacturing process is not changing.

- CDRH may accept filing in an annual report. Note – this is an ongoing evaluation this is developing policy evaluation.
Example: Annual Filing vs 30 Day PMA Notification

Scenario 3: COTS MES Upgrade

• Intended use: Refer to scenario 1. As part of upgrade, adding new features such as process timers (automating manual function, e.g. timers for ovens). The Physical manufacturing process is not changing.

• No customizations. Scripted testing for high risk; unscripted testing for new medium & low risk features.

• Downstream controls to inspect/check product remain.

• Based on downstream controls and risk based assurance approach, device quality, device safety, and patient/user safety risk have been mitigated. CDRH may accept filing in an annual report. Note – this is developing policy evaluation.

Why: FDA’s objective for these efforts is to enable safer and better medical devices for patients and providers, by making it easier, faster, and more value-added for manufacturers to deploy the necessary automation.
## Automated Computer System Validation Tools

<table>
<thead>
<tr>
<th>Function</th>
<th>Intended Use</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Software testing tool measuring system behavior and performance under load</strong></td>
<td>Used for testing the performance of new manufacturing automations under load</td>
<td>*Loadrunner, ApacheJMeter</td>
</tr>
<tr>
<td><strong>Automated functional graphical user interface (GUI) testing tool that allows a user to record and play back user interface (UI) interactions as test scripts.</strong></td>
<td>Used for developing a test script based on user interactions to automate future testing of UI modifications</td>
<td>*Winrunner, Ranorex</td>
</tr>
<tr>
<td><strong>Bug tracking, issue tracking, and project management systems.</strong></td>
<td>Used for rapidly capturing issues and bugs found during assurance testing</td>
<td>*Jira, Confluence</td>
</tr>
<tr>
<td><strong>Manage and track the application lifecycle development process. Includes, risk, test, and the respective change control/approval of applications</strong></td>
<td>Used for tracking and monitoring all stages of new IT system implementations, throughout the lifecycle.</td>
<td>*Polarion ALM, PTC Integrity</td>
</tr>
<tr>
<td><strong>Dynamic web performance evaluation tool.</strong></td>
<td>Used for testing the performance of web-based User Interfaces</td>
<td>*Dynatrace AJAX Edition, New Relic APM</td>
</tr>
</tbody>
</table>

*All product trademarks, registered trademarks or service marks belong to their respective holders.

Manufacturer is using these tools to automate and supplement tracking and assurance testing for non-product systems. These intended uses of these tools do not have a direct impact on device quality and device safety.
Qualification of Automated CSV Tools
Example 1 – Code Debugger

A CAPA automation system is being written in Java script and a developer tool is used to set up breakpoints and step through of the code. Once the code is debugged all the debugger content is removed prior to the promotion of the code to the production system. The debugger tool is not part of production or the quality systems.

Step 1: Identify where and how the Debugger will be used within your organization

Step 2: Determine if the intended use for automating part of production or the quality system

Consider the following in your decision, then capture the decision with rationale
• The off-the-shelf tool is not part of or integrated with the production or the quality system

Step 3: Assure the use within your organization

Assurance of the code debugger tool includes testing the tool for use within your organization.

1. Identify or create code to be debugged with known error types
2. Execute the debugger and verify that all expected error types manifested
3. Correct the errors in the code and execute the code to verify that the debugger produced executable code to meet your use.

Step 4: Evidence

Record the intended use decision and rationale, as well as the acceptance conclusion for the tool.
Qualification of Automated CSV Tools

Example 2 – Automated Testing Tool

An ERP system has a load requirement and HP Loadrunner is used to simulate anticipated peak load of the production system. The load testing results assures that the system can absorb the required user load. Then the automated testing tool used to test load to a production system is not part of production or the quality systems.

Step 1: Identify where and how the testing tool will be used within your organization.

Step 2: Determine if the intended use for automating part of production or the quality system

Consider the following in your decision, then capture the decision with rationale:

- The testing tool is not the system of record of the product testing results
- The test tool does not alter the code within the production system
- The testing does not add any data to the production system
- The tool is not used for verification of Medical Device

Step 3: Assure the use within your organization

Assurance of the automated testing tool includes testing the tool for use within your organization.

1. Identify the type of testing results that will be achieved with the testing tool
2. Execute known test cases that represent a solid sampling of test types and conditions that will be encountered during use.
3. Ensure that the testing tool produced the testing results that were expected to meet the testing requirement of your organization that will minimize defects being introduced into a production environment for your organization.

Step 4: Evidence

Record the intended use decision and rationale, as well as the acceptance conclusion for the tool.
Qualification of Automated CSV Tools
Example 3 – Defect management and ALM tools

A medical device company uses Polarion to automate the company’s CSV process including testing, defect management and other software life cycle functionality in the support of implementation of a quality production system. The activities performed, and records maintained in Polarion support the execution of the company CSV procedure and is part of the quality systems.

Step 1: Identify where and how a Defect Management and ALM tool will be used within your organization

Step 2: Determine if the intended use for automating part of production or the quality system

Consider the following in your decision, then capture the decision with rationale that validation is not applicable:

• ALM tool is used to execute company’s CSV process and does not alter the Production system data but automates part of quality system
• ALM tool is configured to automate company’s CSV process and does not impact nor interface with validated production quality systems.
• The testing does not add any data to the production system

Step 3: Assure the use within your organization

FDA considers that impact to the quality system does not present a direct patient or user safety risk. Assurance of the automated testing tool includes testing the tool for use within your organization.

1. Identify specific functionality or process that the ALM or Defect management tool will automate by creating specific functional level requirements.
2. Execute known test cases that represent functional requirements under a variety of conditions that represent organizational use.
3. Ensure that the testing results produced the desired outcome to a level that provides full confidence in the tool(s) functionality to meet the intended use of an ALM or Defect management tool within your organization.

Step 4: Evidence

Record the intended use decision and rationale, testing results, as well as the acceptance conclusion for the tool.
Complaint Handling Spreadsheet example

**Intended Use:** Extract complaint data from plant local systems & identify complaint trends across regions in injectables sources

**Example Requirement:** Global QM shall be able to open read-only complaint data extracts from “xyz” secure storage location.

**Risk Level:** LOW (patient), a configured implementation method

**Spreadsheet Tested:** Spreadsheet X, Version 1.2

**Test Type:** Unscripted Testing

**Goals:**
- Ensure Global QMs are able to open complaint data extracts from “xyz’ secure storage location (data retrievability)
- Ensure complaint data extracts are read-only (data protection testing) and “xyz” storage location is accessible only to authorized individuals (data security testing)

**Assurance activities:**
- Performed data retrievability, data security and data protection testing as outlined in the testing goals. Included positive as well as negative test conditions for testing if unauthorized individuals can access the data.

**Conclusion:** No errors observed.

The intended use was identified to be low patient risk and rapid exploratory testing of specific functions were performed. The resulting record quickly identifies the intended use, what was tested, how it was tested, the test objective, who performed the testing, and conclusion on validation activities.
A medical device firm applies Risk Based Validation to an off the shelf LMS. Qualifying the vendor then applying risk to the feature level allows for much less documented verification activities.

**Basic Assurance / Low Risk Features**
- Ex: Usability Features – training notifications, overdue training lists, curricula assignments.
- Ad Hoc Testing 80%

**Medium Risk Features**
- Ex: Capture evidence of training completion by entering username & password.
- Unscripted Testing 20%

**High Risk Features**
- No High Risk Features
- Scripted Testing 0%
Risk Based CSV Example: Non-Conformance & CAPA Process

A medical device firm applies Risk Based Validation to an off the shelf CAPA System. Qualifying the vendor then applying risk to the feature level allows for much less documented verification activities.

<table>
<thead>
<tr>
<th>Basic Assurance / Low Risk Features</th>
<th>Ex: Usability Features – required data entry from optional data entry, attachments of objects, system workflow, non conformance initiation.</th>
<th>Ad Hoc Testing 30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium Risk Features</td>
<td>Ex: Electronic Signature Features – audit trail, meaning of signature (review, approval).</td>
<td>Unscripted Testing 50%</td>
</tr>
<tr>
<td>High Risk Features</td>
<td>Ex: Product Containment – NC is initiated for product outside of the company’s control, then the system prompts the user to identify if a product recall is then needed.</td>
<td>Scripted Testing 20%</td>
</tr>
</tbody>
</table>