CSA Revolution Series: Computer Software Assurance

DIRECT FROM THE SOURCE – HEAR FROM THE
FDA – INDUSTRY CSA TEAM

(FICSA Team)

Johnson & Johnson
CSA Journey & Case Study MES

Live Webinar Series, Episode 2
Thursday July 23rd, 2020

Khaled Moussally (Host)
EVP, Clients & Regulatory Relations

Ron Schardong (Guest)
Sr. Director, Technology Quality

Melissa Vazquez (Guest)
Manager, Technology Quality

Hosted By
Agenda

- Hear directly from the Source “FDA-Industry CSA Team” (FICSA) Members!
- 2020 Webinar Series Schedule why?
- Johnson & Johnson CSA Journey and Case Study on MES
- Next Steps

Objectives

- Don’t wait for the FDA Draft Guidance to be released
  - Start thinking how you want to implement CSA
  - Pilot Studies Effective
  - Digitize your current paper CSA processes
- Create awareness to accelerate innovation
- Inspire action so you can begin to realize value
Melissa Vazquez is a Technology Quality Manager at Johnson & Johnson responsible for computer system validation and quality oversight of Manufacturing Execution Systems (MES) globally for the Medical Device, Consumer and Pharmaceutical segments. Melissa holds a Master of Science from the University of Medicine and Dentistry of New Jersey, Graduate School of Biomedical Sciences. She has over 20 years of experience in software quality engineering, auditing, technical writing and training, which span across Manufacturing, Laboratory, Clinical, and Quality Systems.

Ron is privileged to lead Johnson & Johnson’s technology quality group responsible for computerized systems validation of business applications in the Medical Devices, Consumer and Pharmaceutical segments worldwide. The applications include ERP, Warehouse Management, Manufacturing, Laboratory, Quality Systems, Clinical, R&D, Enterprise Agile Tools and Infrastructure. He has over 25 years of experience in quality engineering, supplier quality, quality auditing, quality management, regulatory compliance and regulatory affairs. Ron is a member of the “FDA – Industry CSA team”.

Khaled Moussally is a Quality & Compliance executive and a thought leader providing cutting-edge solutions to Life Sciences industry. After spending over 25+ years with corporate in IT, Manufacturing and Quality, Khaled transitioned into consulting to bring about a paradigm shift in Quality & Compliance by leveraging his experience with regulatory agencies. Khaled is a key participant of the MDIC “Case for Quality Initiatives” and a member of the “FDA – Industry CSA team” contributing to the FDA draft guidance “Computer Software Assurance (CSA) for Manufacturing, Operations, and Quality System Software”. Khaled is on the “ISPE GAMP America Steering Committee” and has co-presented with the FDA in numerous industry conferences on how to reduce CSV cycle times while enhancing quality by applying CSA concept.
# FDA - Industry CSA (FICSA) Webinar’s Schedule

<table>
<thead>
<tr>
<th>Company</th>
<th>Date</th>
<th>Episode#</th>
<th>Topic /Guest(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fresenius Medical Care</strong></td>
<td>August 6th</td>
<td>3</td>
<td>Open discussion with Bill D’Innocenzo and Marc Kotter walking through a Fresenius CSA journey with invited guests from the FDA and Siemens</td>
</tr>
<tr>
<td>Medtronic</td>
<td>August 20th</td>
<td>4</td>
<td>Open discussion with Francesca Bill - walking through a Medtronic CSA Case Study Automating Risk Based</td>
</tr>
<tr>
<td><strong>Boston Scientific</strong></td>
<td>September 3rd</td>
<td>5</td>
<td>Open discussion with Ray Murphy &amp; Damien McPhillips - walking through a Boston Scientific CSA Case Study for PM/Calibration System</td>
</tr>
</tbody>
</table>

## CSA Revolution Series: Computer Software Assurance

**DIRECT FROM THE SOURCE – HEAR FROM THE:**

**FDA – INDUSTRY CSA TEAM**

- **Khaled Moussaity** (Host)  
  EVP, Clients & Regulatory Relations, Fresenius Medical Care

- **Bill D’Innocenzo** (Guest) 
  EVP, Digital Integration Global Manufacturing, Quality & Supply, Fresenius Medical Care

- **Marc Koetter** (Guest)  
  Sr. Manager, IT, Fresenius Medical Care

**Mission of FDA – Industry CSA Team**

The mission of this FDA and life science industry CSA Team is to drive a paradigm shift to a leaner, value-driven and patient-focused transformation from CSV to CSA.

## Register for Episode 3 August 6th

- **Francisco (Cisco) Vicenty** (Invited Guest)  
  Program Manager, CDRH, FDA

- **Jason Spiegler** (Invited Guest)  
  Sr Director, Strategic Initiatives, Siemens
CSA Revolution Series
Game Changer Kick Off Webinar Series
Was back on April 23rd, 2020

- Recorded Webinar - CSA Game Changer Webinar with the Cisco Vicenty from FDA Click Here

- Webinar Material - Click Here

- CG/CSA White Paper -
FDA - Industry CSA Team (FICSA)

Contributions also provided by past team members:
Stacey Allen, Jason Aurich, Sean Benedik, Laura Clayton, Bill Hargrave, Joe Hens, Scott Moeller, John Murray, Penny Sangkhavichith, and Dana Guarnaccia

Company | Name
--- | ---
Baxter Healthcare | Tina Koepke
Boston Scientific | Damien McPhillips
Boston Scientific | Ray Murphy
Compliance Group | Khaled Moussally
Edwards Lifesciences | Andy Lee
FDA | Cisco Vicenty
Fresenius Medical Care | Bill D’Innocenzo
Fresenius Medical Care | Curt Curtis
Fresenius Medical Care | Marc Koetter
Gilead Sciences | Ken Shitamoto
Gilead Sciences | Senthil Gurumoorthi
Johnson and Johnson | Ron Schardong
Lantheus Imaging | Lou Poirier
Medtronic | Frankie Bill
Medtronic | Michael Branch
Medtronic | April Francis
NeuroVision Imaging | Pepe Davis
Ortho-Clinical Diagnostics | Des Chesterfield
Siemens Digital Industries | Jason Spiegler
Siemens Digital Industries | Greg Robino
Roche | Thorsten Ruehl
Omnicell | Frank Meledandi Sr.

Join FICSA LinkedIn Group

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Computer Software Assurance

Five Things You Need To Know

Computer Software Assurance (CSA) comes from a multi-year collaboration between FDA and industry. It identifies common pain points; FDA’s current thinking puts patient safety and product quality at the heart of the risk assessment process.

1. Risk is based on the impact to patient safety and product quality measured against requirement complexity.

2. It calls for the least burdensome documentation approach.

3. It reduces paperwork by 80% with unscripted and ad-hoc testing.

4. It results in less issues encountered in Production.

5. FDA & ISPE supported.

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A Paradigm Shift
Channelling John Murray

Benefit of detecting patient risk areas using a more flexible, less burdensome, and faster approach for data mining far exceeds the documentation/time burden of current expectations.

From CSV...
- Focus on creating documentary records for compliance
- “Validate” everything (and miss higher risk areas)
- Ignoring previous assurance activity or related risk controls

To CSA...
- Focus on testing for higher confidence in system performance
- Risk based “Assurance”, applying the right level of rigor for a given level of risk to patient safety and/or product quality
- “Take credit” for prior assurance activity and upstream/downstream risk controls
Our journey through CSA

A few reminders and points to consider

• CSA is not a full SDLC
• Unscripted ≠ No Documentation
• Leveraging software vendor
• Barriers & objections = know your base
• What are we doing to prepare for the release of CSA?
CSA Pilot Strategy Definition

Documented pilot strategy in the Compliance Plan (CP) for each of the 3 sites.

• Validation focused on **Intended Use**
• Used **Agile** method
• Followed a **Risk Based** Approach, C-to-Q (Critical to Quality)
• **2 levels of Assurance Testing Activities:**
  – **Baseline** Assurance
  – **Risk Based** Assurance
• Evidence / **Records**
  – Electronic or Digital vs. no Paper
  – Agile testing and tools
# CSV Activities & Impact

<table>
<thead>
<tr>
<th>CSV Activity</th>
<th>Pre-Pilot</th>
<th>Post-Pilot</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements/User Story (US)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Assessment (RA)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Baseline Assurance</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Installation Qualification (IQ)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Import, Configuration Verification (ICV)</td>
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<td></td>
</tr>
</tbody>
</table>
CSV Activities & Impact (continued)

<table>
<thead>
<tr>
<th>CSV Activity</th>
<th>Pre-Pilot</th>
<th>Post-Pilot</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Testing</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>User Acceptance Testing (UAT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defects /Errors/ Incidents</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

“Systems used in support of manufacturing provide significant benefits in detecting patient risk areas, improving business value, optimizing resources, and enhancing a manufacturer’s capability to deliver on product quality and improving patient health outcomes”
## CSV Activities & Impact (continued)

<table>
<thead>
<tr>
<th>CSV Activity</th>
<th>Pre-Pilot</th>
<th>Post-Pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Changes/ Upgrade</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Agile Concepts</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Changes/ Upgrade
- Introduced electronic change management system for MES Change Control
- Used Change Request record for compliance and testing strategy
- Streamlined Test Scripts for changes
- Significant reduction in Execution, Review & Approval
- Reduced manual tasks (printing, scanning, handwritten/GDPs) and introduced electronic efficiencies (TSs, PSs)

### Agile Concepts
- Sequential CSV Approach
- Separate deliverables
- All in one delivery
- All formal testing in QA
- Parallel Activities
- Combined deliverables
- Iterations for delivery
- Upfront activities (Vendor & Dev. Env)
- Parallel Activities (e.g. IQ and Performance in Production (PD) while ST/UAT executed in QA in parallel for a new PD or new Upgrade Environments)
- Significant streamlining of deliverables & signatures (combined Protocols and Reports for the different testing efforts - IQ, ICV, ST, UAT for QA and PD; URS & RA)
- Scalable and Incremental releases (functionality and/or configuration) to speed to value
- Executed functional and configuration testing in the Vendor QA (J&J equiv.) and/or J&J Dev Environments to jumpstart and/or streamline testing
- Standard structure for Jira, HP ALM and ClearQuest and promoted leveraging content and deliverables across MES efforts
- Guidance documents for electronic tools
Executive Summary
The MES Pilot using the CSA (Computerized System Assurance) principles proved to be a significant step towards streamlining CSV and enabling high-quality manufacturing.

<table>
<thead>
<tr>
<th>Agile concepts and automated tools significantly reduced <strong>Documentation</strong>.</th>
<th>Formal <strong>Testing</strong> reduced and focused on Critical to Quality requirements.</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Time</td>
<td>✓ Cycle Time</td>
</tr>
<tr>
<td>✓ Paper</td>
<td>✓ Config testing (90% formal)</td>
</tr>
<tr>
<td>✓ Manual Errors</td>
<td>✓ Install testing (50%)</td>
</tr>
<tr>
<td>✓ Signatures/Approvals</td>
<td>✓ Unnecessary/tedious steps</td>
</tr>
<tr>
<td>✓ Use of Automated tools</td>
<td>✓ Non-value added Defects</td>
</tr>
<tr>
<td>✓ Visibility</td>
<td>✓ C-to-Q Testing Analysis</td>
</tr>
<tr>
<td>✓ Standardization</td>
<td>✓ Dev testing (Config)</td>
</tr>
<tr>
<td>✓ Efficiency</td>
<td>✓ Parallel Activities</td>
</tr>
<tr>
<td>✓ Use of Automated tools</td>
<td>✓ Better use of SMEs time</td>
</tr>
<tr>
<td>✓ Visibility</td>
<td>✓ Agile methods adoption</td>
</tr>
<tr>
<td>✓ Standardization</td>
<td>✓ Dedicated Team (synergy/responsiveness)</td>
</tr>
</tbody>
</table>

“Approach to promote the application of critical thinking and a commensurate risk-based consideration to the level of testing and documentation” -FDA
Next Steps

- Don’t wait for the FDA Draft Guidance to be released
  - Start thinking how you want to implement CSA
  - Pilot Studies Effective
  - Digitize your current paper CSA processes (See appendix)
- Create awareness to accelerate innovation
- Inspire action so you can begin to realize value
Questions?

Contacts

Ron Schardong - RSchard9@ITS.JNJ.com
Melissa Vazquez - MVazqu10@its.jnj.com
Khaled Moussally - khaled@complianceg.com
The Meat - “FDA - Industry CSA Team Recommendations”

**Note:** All of these recommendations are within FDA Regulations!
Focus on Assurance

Shift the discussion
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
## 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>
</table>
| **Unscripted Testing:** Ad-hoc (with least-burdensome documentation) | • Testing of features and functions with no test plan | • Details regarding any failures/deviations found | • Summary description of features and functions tested  
• Issues found and disposition  
• Conclusion statement  
• Record of who performed testing and date |
| **Unscripted Testing:** Error guessing | • Testing of feature and function fail-modes with no test plan | • Details regarding any failures/deviations found | • Summary description of fail-modes tested  
• Issues found and disposition  
• Conclusion statement  
• Record of who performed testing and date |
| **Unscripted Testing:** Exploratory Testing | • Establish high level test plan objectives for features and functions *(no step-by-step procedure is necessary)* | • Pass/fail for each test plan objective  
• Details regarding any failures/deviations found | • Summary description of features and functions tested  
• Result for each test plan objective – only indication of pass/fail  
• Issues found and disposition  
• Conclusion statement  
• Record of who performed testing and date |
| **Scripted Testing:** Limited | • Limited Test cases (step-by-step procedure) identified  
• Expected results for the test cases  
• Identify unscripted testing applied  
• Independent review and approval of test plan. | • Pass/fail for test case identified  
• Details regarding any failures/deviations found and disposition regarding fails | • Summary description of features and functions tested  
• Result for each test case - only indication of pass/fail  
• Issues found and disposition  
• Conclusion statement  
• Record of who performed testing and date  
• Signature and date of appropriate signatory authority |
| **Scripted Testing:** Robust | • Test objectives  
• Test cases (step-by-step procedure)  
• Expected results  
• Independent review and approval of test cases. | • Pass/fail for test case  
• Details regarding any failures/deviations found and disposition regarding fails | • Detailed report of assurance activity  
• Result for each test case - only indication of pass/fail  
• Issues found and disposition  
• Conclusion statement  
• Record of who performed testing and date  
• Signature and date of appropriate signatory authority |
PAPERLESS VALIDATION TOOL
Polarion CSA Package

Shorter Cycle Times

Compliant

CSA Methodology

Paperless / Contactless

Industry Leading ALM

Siemens Polarion

Siemens Polarion CSA Template

- Ready to deploy
- Zero footprint
- 100% paperless CSA
Key Lesson #2—
No better time to go paperless/contact-less

“Siemens Polarion is a state-of-the-art ERES compliant paperless/contact-less validation system which has a CSA workflow and templates built in.”

- Low cost
- Zero footprint
- 100% paperless CSA
No Of User Requirements In Each Risk Rating

*Info: Pie Chart shows total number of user requirements per Risk Rating*
[User Requirements that are in Draft, Approval, Approved and Obsolete status]

User Requirement / Risk Rating

- Risk Rating - 5
- Risk Rating - 4
- Risk Rating - 3
- Risk Rating - 2
- Risk Rating - 1

Test Run Summary

- 2 Test Runs Executed
- 0 Open
- 0 In Progress
- 0 Reopened
- 1 Passed
- 1 Failed
- 0 Verified Passed
- 0 Verified Failed
- 0 Rejected

- 20 Issues Reported
- 0 Resolved
- 20 Unresolved
- 15 Passed
- 20 Failed

Defects Trends (30 days)
## Risk-Based Test Strategy Report

<table>
<thead>
<tr>
<th>ID</th>
<th>User Requirement</th>
<th>Risk Rating</th>
<th>Testing Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAM-1375</td>
<td>UUR-01: Electrical Power voltage of 120VAC</td>
<td>3</td>
<td>Unscripted Testing - Error Guessing</td>
</tr>
<tr>
<td>RAM-1373</td>
<td>UDR-01: Equipment shall come with a manufacturer’s manual.</td>
<td>5</td>
<td>Robust Scripted Testing</td>
</tr>
<tr>
<td>RAM-1369</td>
<td>UEO-02: System shall perform to meet cleanroom environment requirements.(Equipment Operational Requirements )</td>
<td>5</td>
<td>Robust Scripted Testing</td>
</tr>
<tr>
<td>RAM-1368</td>
<td>UEO-01: System shall draw air into the Portable Hood System</td>
<td>2</td>
<td>Unscripted Testing - Exploratory</td>
</tr>
<tr>
<td>RAM-1366</td>
<td>USR-01: General Safety Requirements are not needed for this equipment</td>
<td>2</td>
<td>Unscripted Testing - Exploratory</td>
</tr>
<tr>
<td>RAM-1364</td>
<td>UGD-01: System shall have adjustable wing flaps.</td>
<td>3</td>
<td>Unscripted Testing - Error Guessing</td>
</tr>
<tr>
<td>RAM-1362</td>
<td>UGR-01: System shall have filters.</td>
<td>1</td>
<td>Vendor Audit and Assurance</td>
</tr>
</tbody>
</table>

## Requirements Status Report

- 28 in Approval
- 7 Approved
- 7 Rejected
- 2 In Draft
- 3 Complete

## Defects by Status

- 28 In Approval
- 7 Approved
- 2 Rejected
- 3 Complete