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
COMPLIANCE GROUP

Ron Schardong (Guest)
Sr.Director, Technology Quality
Johnson & Johnson

Melissa Vazquez (Guest)
Manager, Technology Quality
Johnson & Johnson

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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- Don't wait for the FDA Draft Guidance to be released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

FDA - Industry CSA (FICSA) Team Members

Ron Schardong

SR. DIRECTOR, TECHNOLOGY QUALITY - CSV

Johnson & Johnson

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"***

Melissa Vazquez

MANAGER, TECHNOLOGY QUALITY - CSV

Johnson & Johnson

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.

Khaled Moussally

EXECUTIVE VICE PRESIDENT CLIENTS & REGULATORY RELATIONS

COMPLIANCE GROUP

Khaled 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

Company	Date	Episode#	Topic /Guest(s)
FRESENIUS MEDICAL CARE	August 6th	3	Open discussion with Bill D'Innocenzo and Marc Kotter walking through a Fresenius CSA journey with invited guests from the FDA and Siemens
Medtronic	August 20th	4	Open discussion with Francesca Bill - walking through a Medtronic CSA Case Study Automating Risk Based
Boston Scientific Advancing science for life™	September 3rd	5	Open discussion with Ray Murphy & Damien McPhillips - walking through a Boston Scientific CSA Case Study for PM/Calibration System

[Register for Episode 3 August 6th]

Invited! Guests

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

Jason Spiegler (Invited Guest)
Sr Director, Strategic Initiatives
SIEMENS
Ingenuity for life

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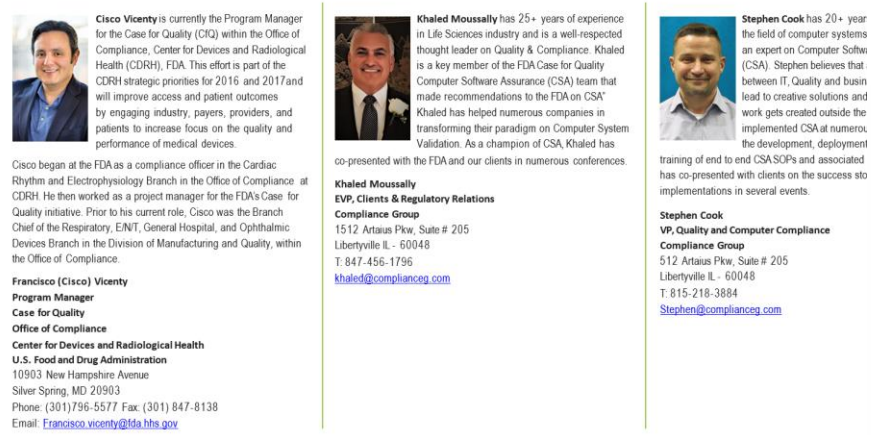
FDA - Industry CSA (FICSA) Team Members

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** -



Panelists

Cisco Vicenty is currently the Program Manager for the Case for Quality (CfQ) within the Office of Compliance, Center for Devices and Radiological Health (CDRH), FDA. This effort is part of the CDRH strategic priorities for 2016 and 2017and will improve access and patient outcomes by engaging industry, payers, providers, and patients to increase focus on the quality and performance of medical devices.

Cisco began at the FDA as a compliance officer in the Cardiac Rhythm and Electrophysiology Branch in the Office of Compliance at CDRH. He then worked as a project manager for the FDA's Case for Quality initiative. Prior to his current role, Cisco was the Branch Chief of the Respiratory, E/N/T, General Hospital, and Ophthalmic Devices Branch in the Division of Manufacturing and Quality, within the Office of Compliance.

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Khaled Moussally has 25+ years of experience in Life Sciences industry and is a well-respected thought leader on Quality & Compliance. Khaled is a key member of the FDA Case for Quality Computer Software Assurance (CSA) team that made recommendations to the FDA on CSA" Khaled has helped numerous companies in transforming their paradigm on Computer System Validation. As a champion of CSA, Khaled has co-presented with the FDA and our clients in numerous conferences.

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Stephen Cook has 20+ year the field of computer systems an expert on Computer Softw (CSA). Stephen believes that between IT, Quality and busin lead to creative solutions and work gets created outside the implemented CSA at numerou the development, deployment training of end to end CSA SOPs and associated has co-presented with clients on the success sto implementations in several events.

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FDA - Industry CSA Team (FICSA)

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

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Company	Name
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 Meledandri Sr.

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

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Computer Software Assurance

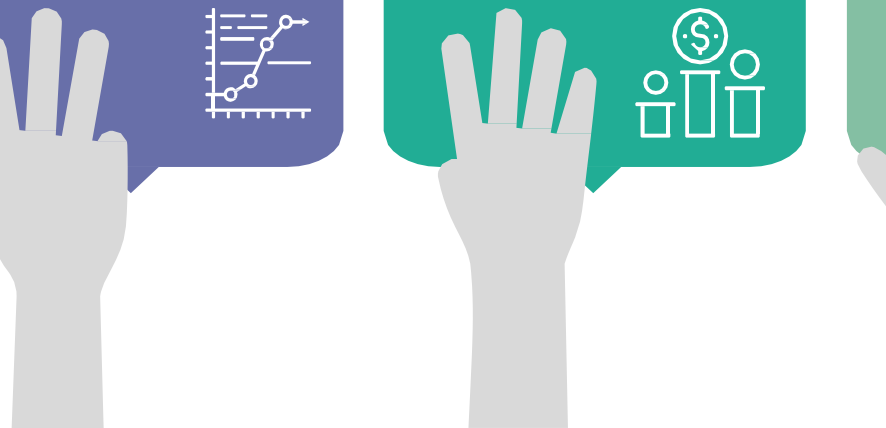
Five Things You Need To Know

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 paper-work 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.

80% Time Spent on Documentation

20% Time Spent on Testing

From CSV...

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

20% Time Spent on Documentation

80% Time Spent on Testing

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

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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

CSV Activity	Pre-Pilot	Post-Pilot	Results
Requirements/User Story (US)			
Risk Assessment (RA)			
Baseline Assurance			
Installation Qualification (IQ)			
Import, Configuration Verification (ICV)			

CSV Activities & Impact (continued)

CSV Activity	Pre-Pilot	Post-Pilot	Results
System Testing			
User Acceptance Testing (UAT)			
Defects /Errors/ Incidents			

"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)

CSV Activity	Pre-Pilot	Post-Pilot	
Changes/ Upgrade			
Agile Concepts			

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.

Agile concepts and automated tools significantly reduced **Documentation**.

- ✓ **Time**
- ✓ **Paper**
- ✓ **Manual Errors**
- ✓ **Signatures/ Approvals**

- ✓ **Use of Automated tools**
- ✓ **Visibility**
- ✓ **Standardization**
- ✓ **Efficiency**

Formal **Testing** reduced and focused on Critical to Quality requirements.

- ✓ **Cycle Time**
- ✓ **Config testing (90%formal)**
- ✓ **Install testing (50%)**
- ✓ **Unnecessary/tedious steps**
- ✓ **Non-value added Defects**

- ✓ **C-to-Q Testing Analysis**
- ✓ **Dev testing (Config)**
- ✓ **Parallel Activities**
- ✓ **Better use of SMEs time**
- ✓ **Agile methods adoption**
- ✓ **Dedicated Team (synergy/ responsiveness)**

"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

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Khaled Moussally - khaled@complianceg.com

BONUS MATERIAL / APPENDIX SLIDES

The Meat - “FDA - Industry CSA Team Recommendations”

Note: All of these recommendations are within FDA Regulations!

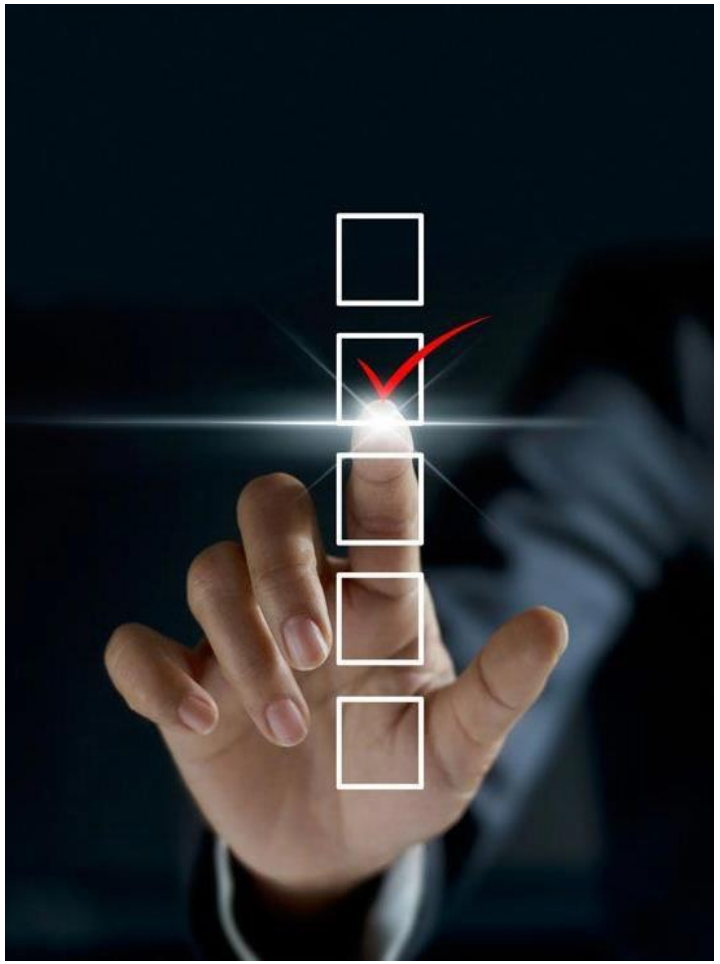
Focus on Assurance

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

Assurance Approach	Test Plan	Test Results	Record (Digital Acceptable)
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

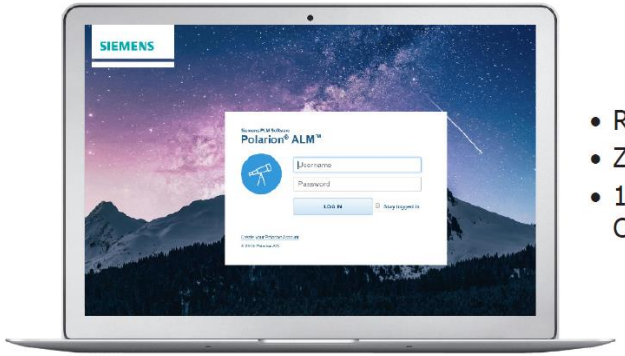
CSA Methodology

Paperless / Contactless

Industry Leading ALM

Siemens Polarion

Siemens Polarion CSA Template



- Ready to deploy
- Zero foot print
- 100% paperless CSA

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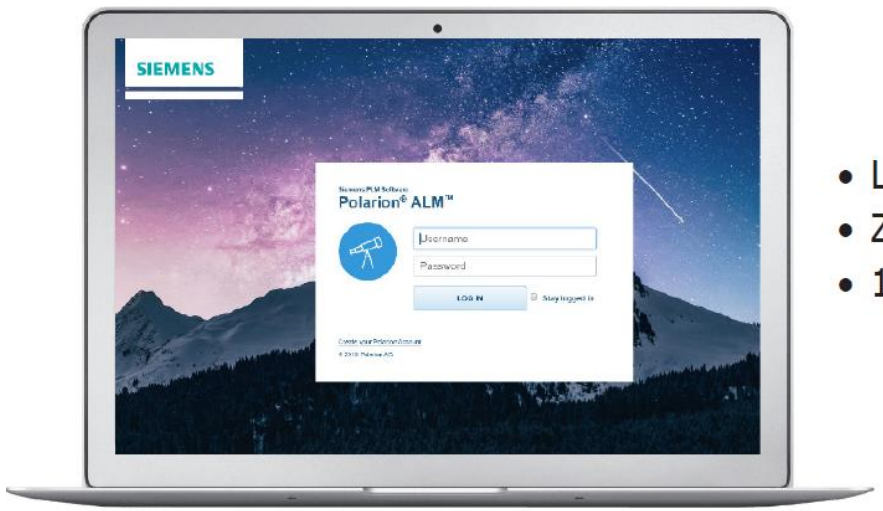
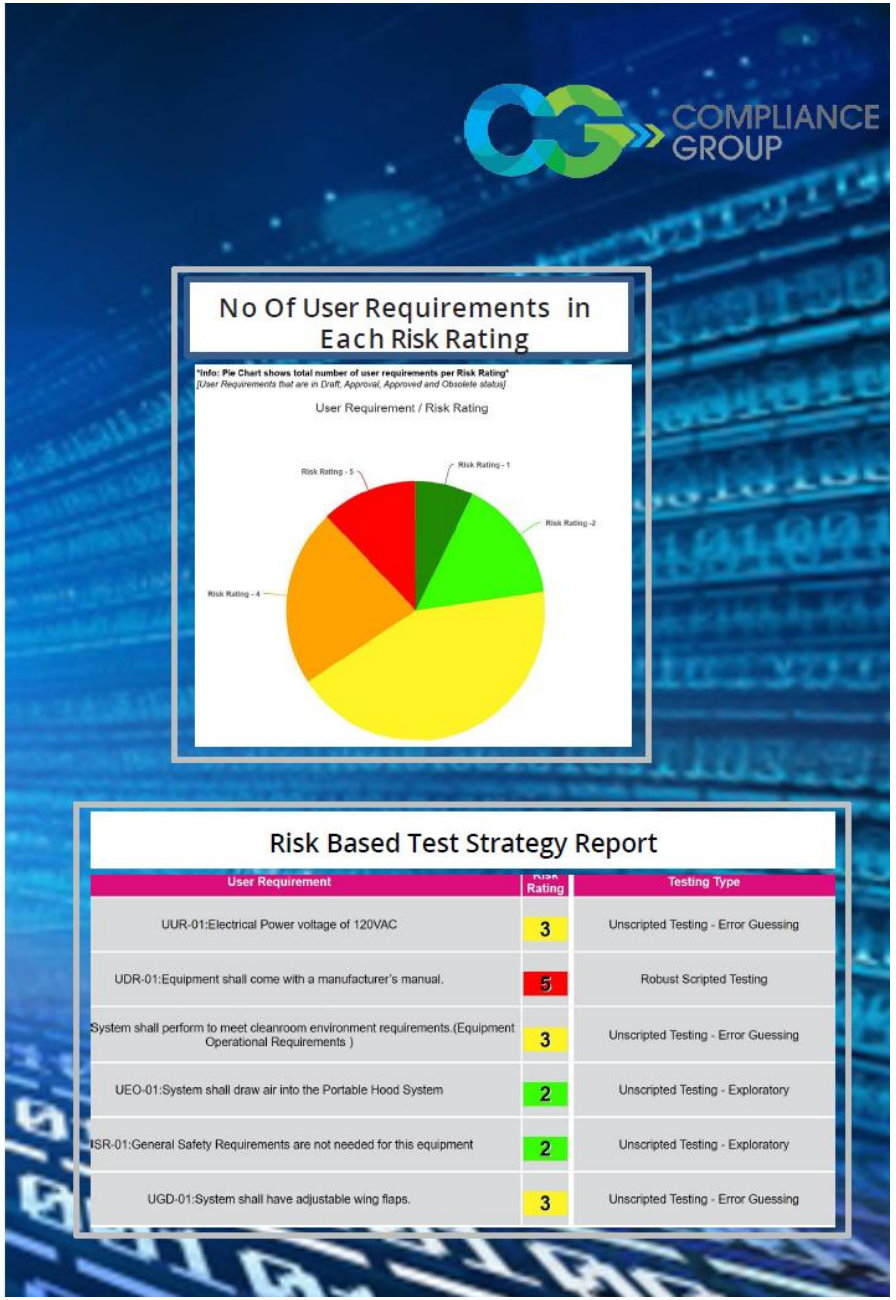
Key Lesson #2– No better time to go paperless/contact-less

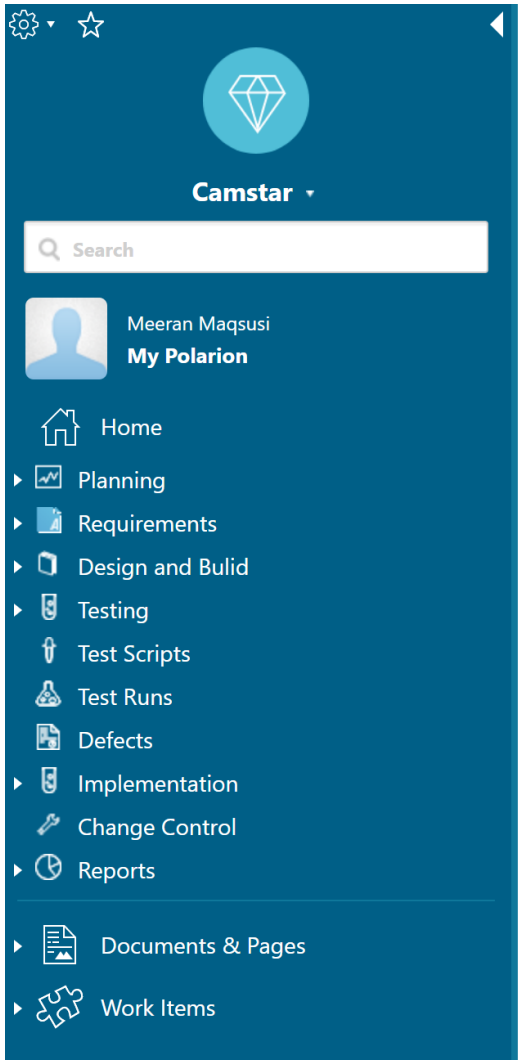
"Siemens Polarion is a state of the art ERES compliant paperless / contact-less validation system which has a CSA workflow and templates built in."



- Low cost
- Zero foot print
- 100% paperless CSA

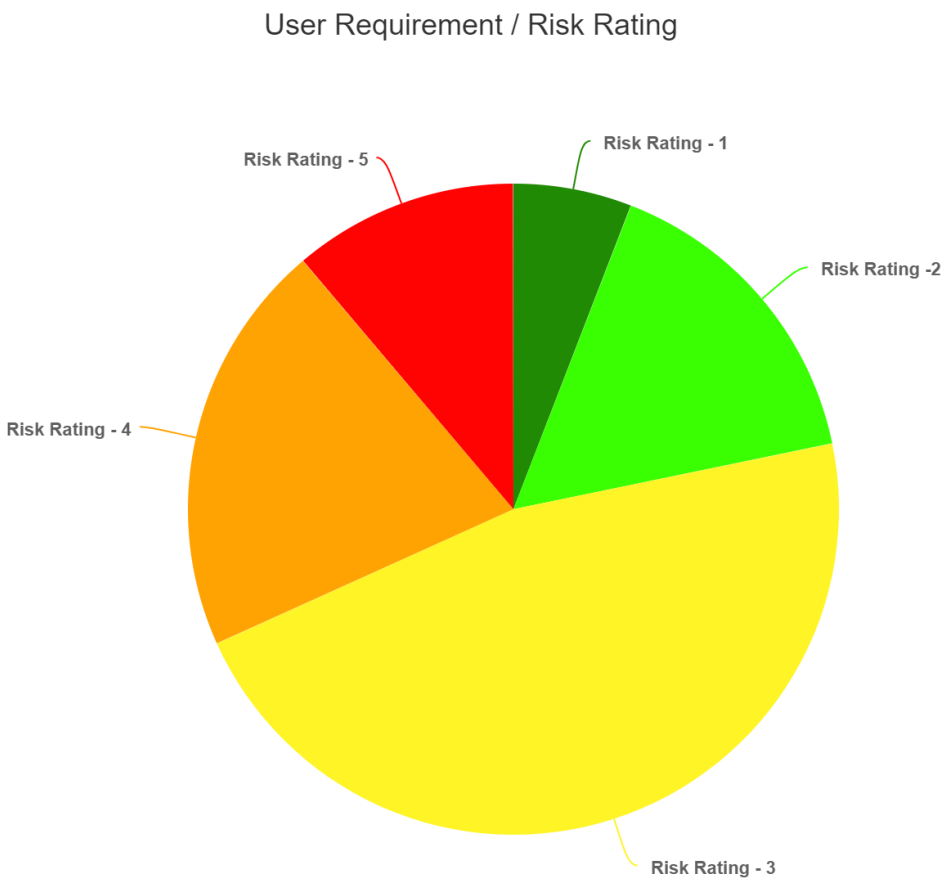


Polarion CSA Screenshots



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]



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

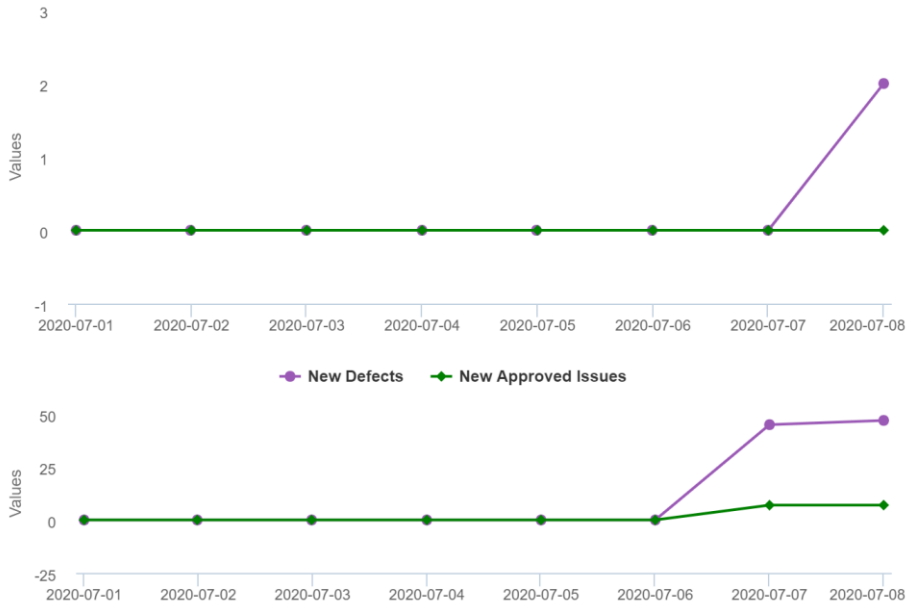
20 Unresolved

35 Executed Test Cases

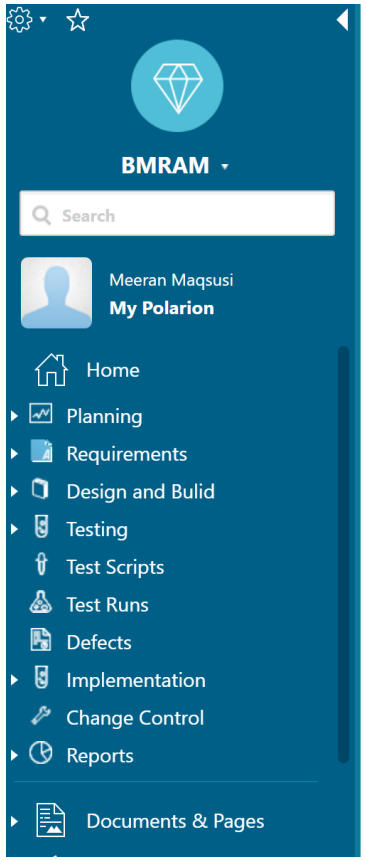
15 Passed | 20 Failed

0 Blocked

Defects Trends (30 days)



Polarion CSA Screenshots



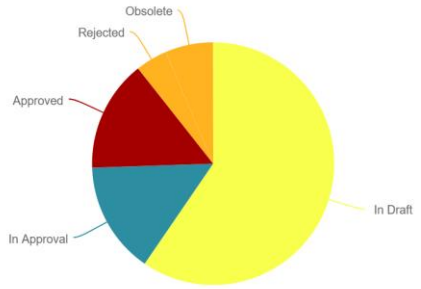
Expand Tools

Risk-Based Test Strategy Report

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

Requirements Status Report

Info: Displays Work Items filtered by Work Item type and grouped by Status.



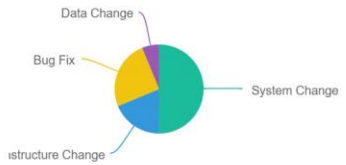
28 In Draft | 7 In Approval | 7 Approved | 2 Rejected | 3 Obsolete

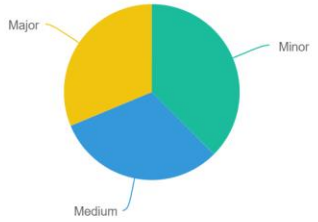
Defects by Status

28 In Draft | 7 In Approval | 7 Approved | 2 Rejected | 3 Obsolete

Change Type Report

Change Request by Change Type



Change Severity Report

Change Request by Change Severity