CSA Revolution Series: Computer Software Assurance

DIRECT FROM THE SOURCE – HEAR FROM THE

FDA – INDUSTRY CSA TEAM

(FICSA Team)

Gilead CSA Journey

Live Webinar Series, Episode 2

Thursday July 9th, 2020

Khaled Moussally (Host)
EVP, Clients & Regulatory Relations
COMPLIANCE GROUP

Ken Shitamoto (Guest)
Sr Director, IT
GILEAD

Senthil Gurumoorthi (Guest)
Director, IT
GILEAD

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Agenda

- Hear direct from the Source "FDA-Industry CSA Team" (FICSA) Members!
- 2020 Webinar Series Schedule
- Gilead CSA Challenge and Success

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- Don't wait for the FDA Draft Guidance to be released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

Senthil Gurumoorthi

DIRECTOR, IT

GILEAD

Senthil leads IT Quality Assurance function at Gilead Sciences, which provides independent oversight for GxP IT Infrastructure, Applications & Platforms and manages Vendor Oversight, IT Inspection and audit readiness programs. He has over 17 years of diverse experience in biopharmaceutical business ranging from pre-clinical, R&D to manufacturing with leadership expertise on Quality Assurance, Risk Management, Inspection/Audit Management, and Vendor Management. Additionally, as certified Auditor conducted ISO and Part 11/Annex 11 Audits globally.
He holds B.E in Electronics & Communication from PSG College of Technology, MS in Electrical Engineering from New Jersey Institute of Technology and Masters in Business Administration (MBA) from Imperial College London

Ken Shitamoto

SR. DIRECTOR, IT

GILEAD

Ken leads the IT quality engineering function at Gilead Sciences, which performs software quality assurance (testing), validation, and infrastructure qualification. He is a multi-disciplined professional with extensive experience in quality engineering, quality management, project management, and software development. He has been in the biopharmaceutical space since 1993 and has worked both on the manufacturer, vendor, and consulting sides of the business. Additionally, he has also performed over 100 GXP computer systems compliance audits globally. He holds a BA Molecular Cell Biology and MS Computer Science and from UC Berkeley and San Jose State University respectively. He is an avid supporter of the American Lung Association, and Ken and his daughter have raised over 130K dollars to fight lung disease

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)
Johnson & Johnson	July 23rd	3	Open discussion with Ron Schardong and Melissa Vazquez - walking through a J&J's CSA case study for MES
Fresenius Medical Care	August 6th	4	Open discussion with Bill D'Innocenzo walking through a Fresenius CSA journey
Medtronic	August 20th	5	Open discussion with Francesca Bill - walking through a Medtronic CSA Case Study Automating Risk Based
Boston Scientific	September 3rd	6	Open discussion with Ray Murphy & Damien McPhillips - walking through a Boston Scientific CSA Case Study for PM/Calibration System
TBD	September 17th	7	TBD
TBD	October 01st	8	TBD
TBD	October 15th	9	TBD
TBD	October 29th	10	TBD

Register for Episode 3- July23rd

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FDA - Industry CSA (FICSA) Team Members

CSA Revolution Series

Game Changer Kick Off

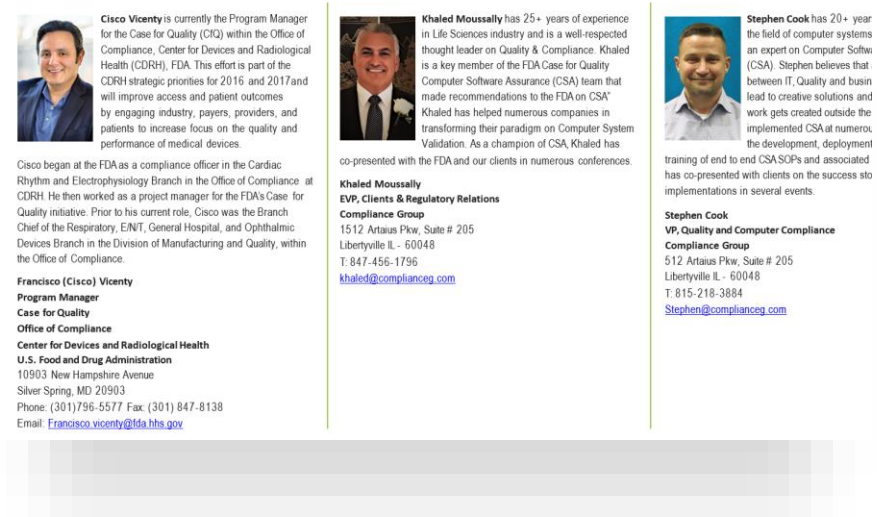
Episode 1

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** -



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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

[Join FICSA LinkedIn Group]

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

Cultural Barriers Paralyzing Industry

Summary of Impact

- Manufacturers are reluctant to invest
- When they invest, the documentation burden is excessive (not commensurate with Risk) impacting "Time to Value"
- Cybersecurity (Enterprise) risk increases
- Slow to upgrade/ implement patches due to "revalidation" lifecycle burden
- Impacts all Centers across FDA!

For software not used in product, manufacturers refer to significantly more burdensome guidance (20+ years old), based on Fear of a 483s, based on prior FDA Investigations and 3rd Party Consultants.

"We are risk-based… everything is high risk!"

"Too much documentation – lot of overhead for little value!"

"It took 4x longer for CSV than the actual analysis!"

"Data mining? We looked at purchasing an inexpensive BI tool, but CSV cost was too high."

"We validate all Software… like product Software!"

"Most deviations are documentation errors, not Software bugs - we trip over ourselves!"

"What if analysis not practical to maintain"

"The real pain no one discusses, is the CSV burden over the lifecycle of maintaining software."

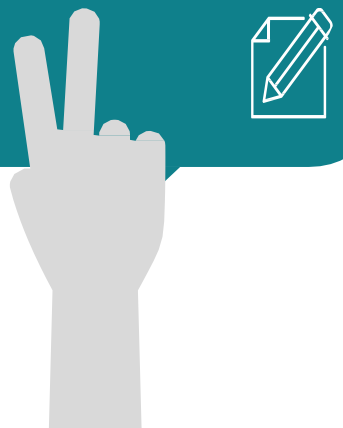
Computer Software Assurance

Five Things You Need To Know

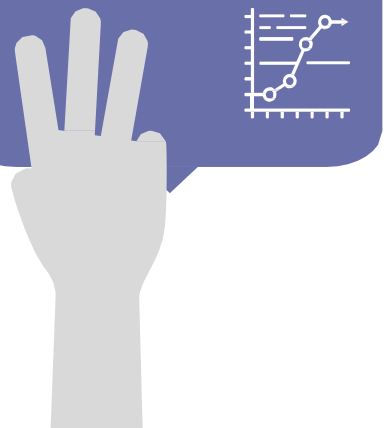
Computer Software Assurance (CSA) comes from a multi-year collaboration between FDA and industry. It identifies common pain points; FDA's current thinking puts patient safety and product quality at the heart of the risk assessment process.

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...

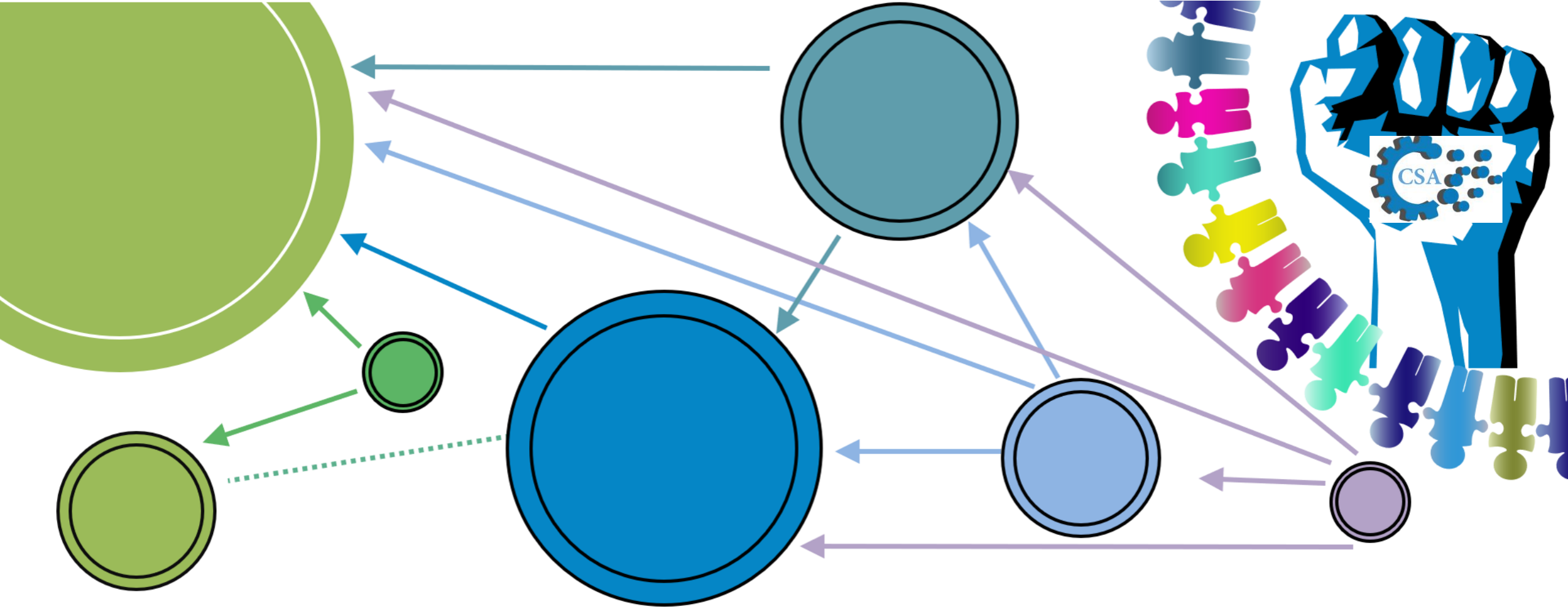
- Focus on creating documentary records for compliance
- "Validate" everything (and miss higher risk areas)
- Ignoring previous assurance activity or related risk controls

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



1997
- 21 CFR 11
- General Principles of SW Validation DRAFT (CDRH)

1999
- CS Used in Clinical Trials (CDER, CBER, CDRH)

2002
- General Principles of SW Validation (CDRH)

2003
- 21 CFR 11 Scope and Application (CDER, CBER, CDRH)

2007
- CS Used in Clinical Investigations (CDER, CBER, CDRH)

2017
- CPG 7348.810 Bioresearch Monitoring

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 (See appendix)
- Create awareness to accelerate innovation
- Inspire action so you can begin to realize value

Questions?

Contacts

Ken Shitamoto Ken.Shitamoto@gilead.com

Senthil Gurumoorthi Senthil.Gurumoorthi@gilead.com

Khaled Moussally - khaled@complianceg.com

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BONUS MATERIAL / APPENDIX SLIDES

The Meat - “FDA - Industry CSA Team Recommendations”

Note: All of these recommendations are within FDA Regulations!

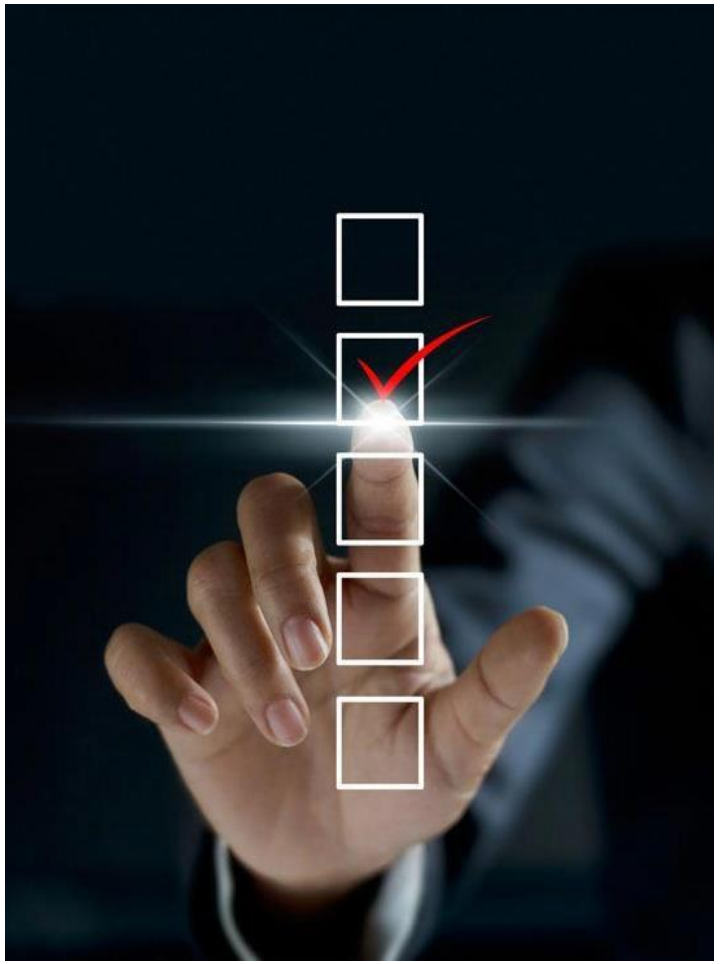
Focus on Assurance

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

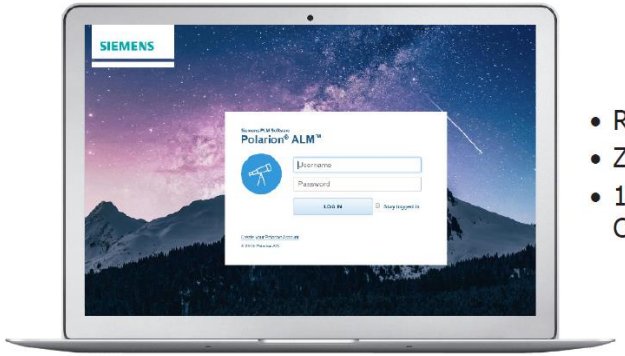
+

Paperless / Contactless

Industry Leading ALM

Siemens Polarion

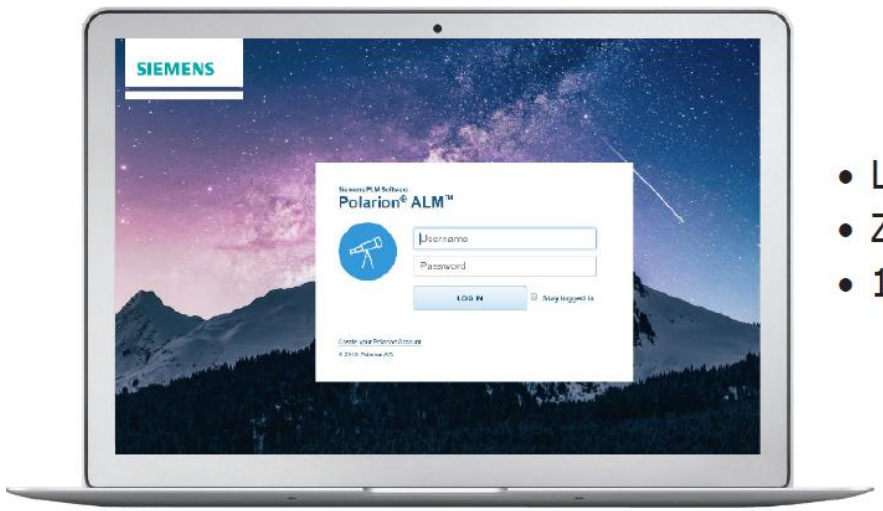
Siemens Polarion CSA Template



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

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

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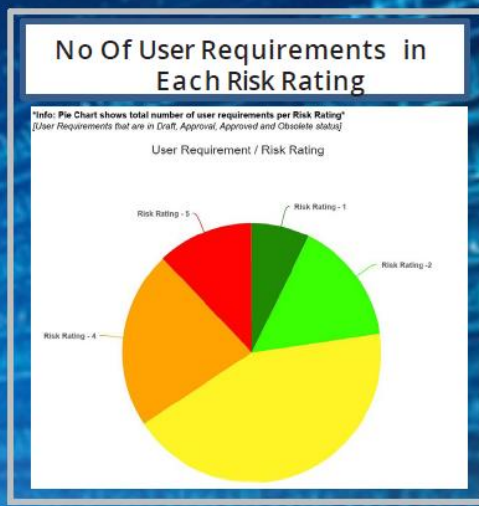
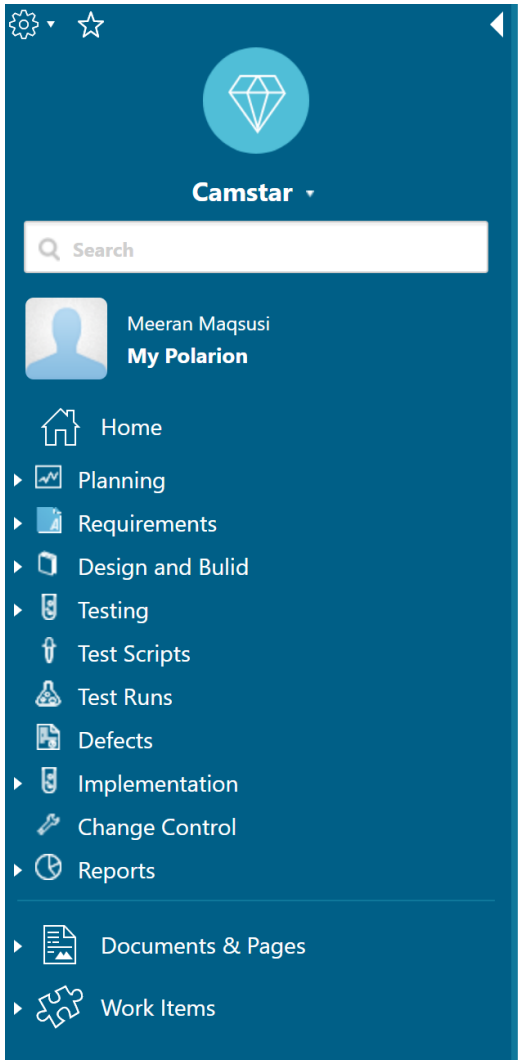


Risk Based Test Strategy Report

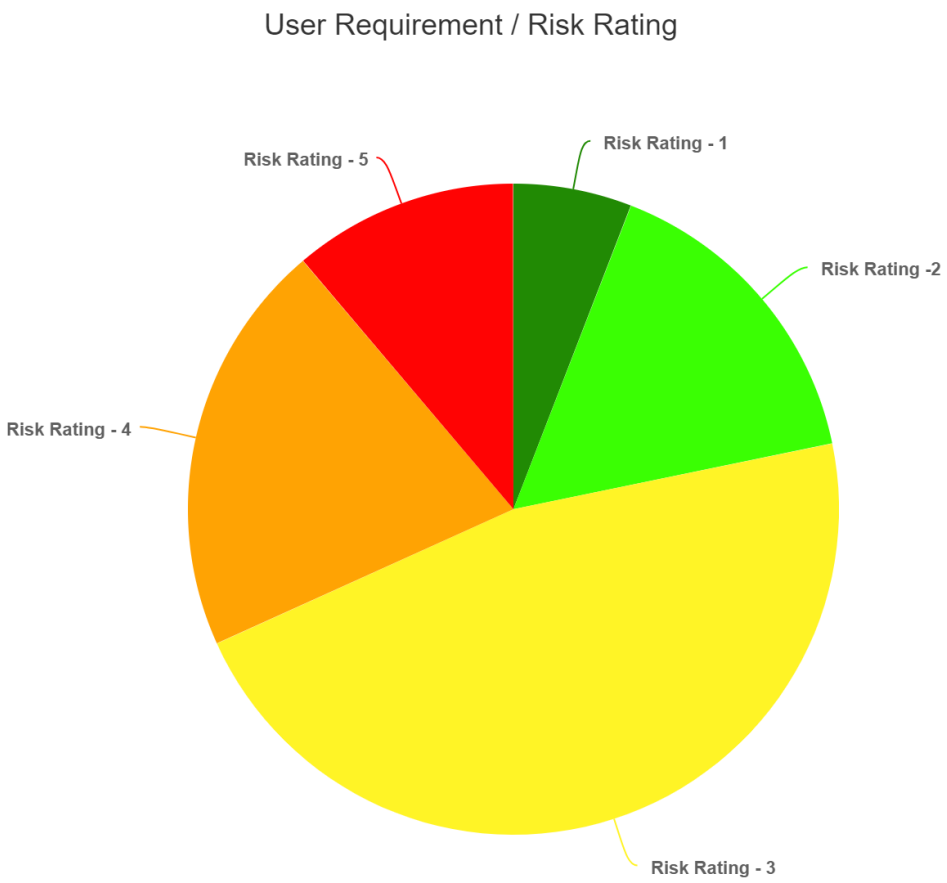
User Requirement	Risk Rating	Testing Type
UUR-01:Electrical Power voltage of 120VAC	3	Unscripted Testing - Error Guessing
UDR-01:Equipment shall come with a manufacturer's manual.	5	Robust Scripted Testing
System shall perform to meet cleanroom environment requirements.(Equipment Operational Requirements)	3	Unscripted Testing - Error Guessing
UEO-01:System shall draw air into the Portable Hood System	2	Unscripted Testing - Exploratory
ISR-01:General Safety Requirements are not needed for this equipment	2	Unscripted Testing - Exploratory
UGD-01:System shall have adjustable wing flaps.	3	Unscripted Testing - Error Guessing

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

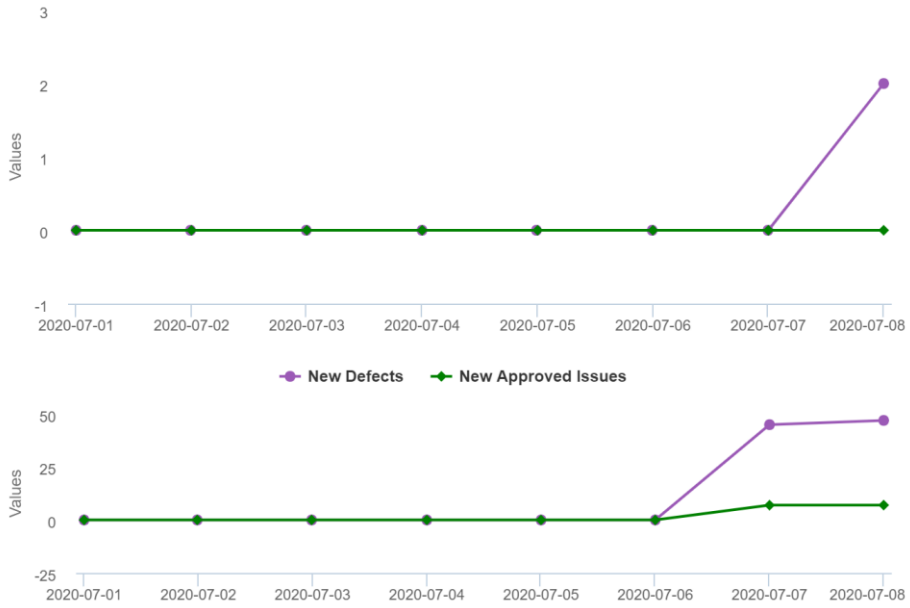
20 Unresolved

35 Executed Test Cases

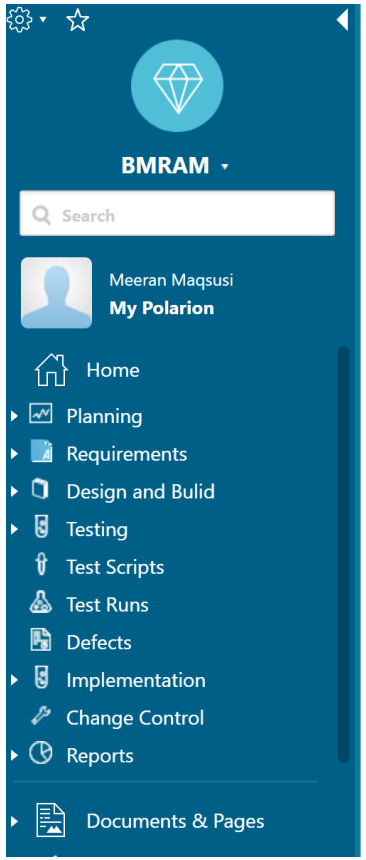
15 Passed **20** Failed

0 Blocked

Defects Trends (30 days)



Polarion CSA Screenshots



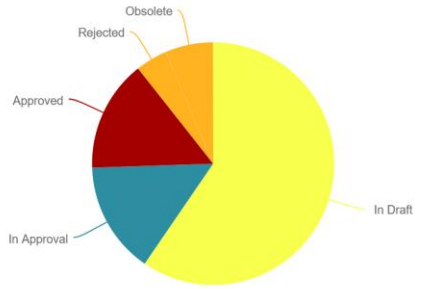
Expand Tools

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.



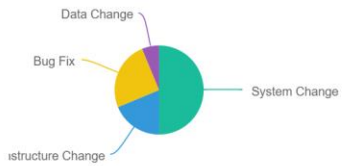
28 In Draft | 7 In Approval | 7 Approved | 2 Rejected | 3 Obsolete

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