Game Changer!
Everything about FDA’s Upcoming Guidance on Computer Software Assurance

Panelists:
Cisco Vicenty, FDA (CDRH)  
Program Manager  
Khaled Moussally, Compliance Group  
EVP, Clients and Regulatory Relations  
Stephen J. Cook, Compliance Group  
VP, Quality and Computer Compliance
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 2017 and 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 the 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+ years of experience in the field of computer systems validation and is an expert on Computer Software Assurance (CSA). Stephen believes that a strong partnership between IT, Quality and business partners can lead to creative solutions and that the really good work gets created outside the SOP. Stephen has implemented CSA at numerous clients including the development, deployment and training of end to end CSA SOPs and associated templates. Stephen has co-presented with clients on the success stories of his CSA implementations in several events.

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Webinar Agenda & Objectives

Overview /Background

CSV Pain Points identified by the Industry to the FDA

How CSA addresses pain points in current CSV approaches

Key Lessons from implementing CSA at numerous companies

Create awareness to accelerate innovation

Inspire action so you can begin to realize value

Leveraging CG’s White Paper

Paperless CSA approaches
2011–2012
FDA Case for Quality Begins

2015 Q2
Siemens – Fresenius Executive Exchange with FDA: CSV Barrier Identified

2016 Q1
Industry team formed/recommendation development begins

2017
Begin promoting recommendations: Zoll Lifevest + Medtronic value examples

2018
• FDA “A List” status for CSA Draft Guidance
• More examples developed
• More firms applying recommendations (Vericel, ICU Medical, etc.)

2019
• More industry adoption (ICU Medical, Gore MP, JUUL, Regenx, Convatec and many others)
• CSA Success stories

2020
• ISPE GAMP endorsement
• 15+ Manufacturer’s Implementation
• CSA Draft Guidance release targeted for 2020
# The Industry CSV Team

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<td>Baxter Healthcare</td>
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<td>Boston Scientific</td>
<td>Damien McPhillips</td>
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<td>Edwards Lifesciences</td>
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<td>Michael Branch</td>
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<td>April Francis</td>
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<td>Zoll Lifevest</td>
<td>Frank Meledandri Sr.</td>
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Contributions also provided by past team members:
Stacey Allen, Jason Aurich, Sean Benedik, Laura Clayton, Bill Hargrave, Joe Hens, Scott Moeller & Mark Willis
CDRH Proposed Guidances for Fiscal Year 2020 (FY 2020)

A-List: Prioritized Guidance Documents that CDRH Intends to Publish in FY2020

Draft Guidance Topics

- Labeling and Informed Decision Checklist for Breast Implants
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Distinguishing between Medical Device Servicing and Remanufacturing
- Computer Software Assurance for Manufacturing, Operations, and Quality System Software
- Procedures for Handling Post-Approval Studies Imposed by PMA Order (revision)
- Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act (revision)


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What has Computer System Validation become?

CSV has morphed into an activity that is done primarily to secure evidence for auditors, rather than to assure the quality of systems.

Validation is synonymous with documentation and delay, and it is often characterized as a necessary evil vs. a value-added activity.

The industry uses regulatory burden (e.g., Data integrity) as an excuse for resisting progress; meanwhile, other regulated and non-regulated industries have moved forward and adopted frameworks for modern testing.
CSV Pain Points – Identified by the Industry to the FDA

1. Deterrent to pursuing automation
2. Focus of CSV on gathering evidence for auditors
3. Duplication of vendor efforts at client site
4. Burdenome and complex Risk Assessments
5. 80% of deviations due to tester or test script errors
6. Numerous post-go-live issues
Impact to medical device ecosystems future state

All efforts to modernize and improve the whole ecosystem, rely on the adoption of technology, datasystems, and practices to create the infrastructure to enable the change. This guidance is foundational!

External Examples
- Advanced Design and Manufacturing Activities
- Digitization/Industry 4.0
- AI and Machine Learning in SaMD
- NEST
- Real World Evidence/Performance
- Patient Outcomes and Value Efforts

FDA Examples
- Case for Quality
  - Voluntary Improvement Program
  - “Safe Space”
  - Product Performance Data, Organizational metrics
- Software Precertification
- Faster signal detection and resolution
- Real-World Data and Metrics
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!”

“We validate all Software... like product Software!”

“Too much documentation – lot of overhead for little value!”

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

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

“What if analysis not practical to maintain”

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

“The real pain no one discusses is the CSV burden over the lifecycle of maintaining software.”
Computer Software Assurance (CSA) comes from a multi-year collaboration between FDA and industry. It identifies common pain points, FDA’s current thinking and 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.
A New Approach to Validation

01 FDA’s VIEW OF AUTOMATION
FDA supports & encourages the use of automation & its solutions

02 PARADIGM SHIFT
Shift focus from documentation to critical thinking and testing

03 TRUSTED VENDORS
Take credit for the work/testing your cloud provider may have done. Ensure it’s a trusted vendor.

04 FOCUS ON INTENDED USE
Clearly define and focus on intended use.

05 USE RISK-BASED TESTING APPROACH
Use streamlined risk-based approach driven by impact to patient/user safety, product quality.

06 UNSCRIPTED TESTING
Focus on testing, not scripting. Use unscripted testing for low/medium risk components.
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
Summary of Benefits

- Reduced cycle times (test creation, review and approval)
- Reduced execution time in QA (IQ 80%, OQ 50%)
- Lower number of defects (script errors, configuration)
- Reduced number of documents (e.g., combining deliverables, test scripts)
- Streamlined approvals (especially for combined deliverables)
- Standardization (strategy, process, project structure)
- Testing focused on ensuring SW Quality (from Dev-PROD)
- Better use of Supplier Qualification
- Maximized use of CSV and Project Resources expertise (e.g., SMEs)
- Capability to deliver value faster (e.g., lower documentation burden and unscripted testing)
Key Lesson #1 – Pilot Studies are effective

“Pilot Study protocols have proven to be a quick and easy way to take advantage of this methodology while also capturing valuable metrics and facilitating team learning/development during protocol planning and execution”
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
Key Lesson #3—Training is key
_workshops work well_

“What we have noted from our many implementations is that “Workshop” based training with practical, real-life samples, are the most effective for bringing cross-functional groups together”
A large number of early adopters in the industry have been socializing and testing CSA principles for 3+ years, with tremendous support and value realization.

**Next Steps:**

- Determine barriers at your company to align to CSA
- Develop Pilot Studies to trial CSA (start small)
- Engage in CSA conferences and webinars
- Contact Compliance Group for help with CSA
- Discuss adoption of paperless / contact-less CSA with Compliance Group (especially due to times like these)*

*Contact Compliance Group for demos of paperless CSA tool Siemens Polarion*
Questions?

Contact
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Stephen Cook
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Why use Compliance Group to help?

CSA may sound easy, until you start blending it in with your existing procedures, and the challenge you face as to which system you can apply it to. Not to mention the organization’s risk tolerance. Compliance Group has successfully implemented various strategies of CSA at ten different clients. From conservative procedures and templates, to ultra-lean, we’ve done them and everything in between.

ComplianceGroup Key Differentiators

- Contributing member of the Industry team that submitted CSA recommendations to FDA
- Contributing to updating ISPE GAMP Good Documentation Guidance Appendix for Data Integrity to leverage CSA
- Successfully implemented various flavors of CSA at 10 different clients
- Validated & remediated hundreds of GxP computerized systems using CSA
- Developed comprehensive set of CSA SOPs and Templates that drastically reduces implementation times
- Ten successful CSA implementations, hundreds of GxP systems validated using CSA that successfully passed inspections.
- Has ready-to-deploy, low cost, paperless / contact-less electronic CSA system (SiemensPolarion)

Reach out to us for flexible full-time, part time resource engagements to help with your CSA journey at sales@complianceg.com