Panel Discussion – KENX, Philadelphia'19

Compliance Intelligence – Stay up to Speed with FDA's proposed Computer Software Assurance Draft Guidance

Panelists:

- Cisco Vicenty, FDA (CDRH), Consumer Safety Office
- Jason Spiegler, Siemens Digital Industries Software Inc., Sr. Director
- Khaled Moussally, Compliance Group, Head of Quality
- Ken Shitamoto, Gilead Sciences – Sr Director, IT

Moderator:

- Senthil Gurumoorthi, Gilead Sciences – Associate Director, IT

During mid-18th century, which one of these metals is considered more precious than the other?

a) Iron
b) Gold
c) Silver
d) Aluminum

d) Aluminum

FDA (The Food and Drug Administration) is the oldest comprehensive consumer protection agency in the US Federal Government?

True

What city was home to the first hospital in the United States?

a) Charity Hospital, New Orleans
b) Bellevue Hospital, New York
c) Pennsylvania Hospital, Philadelphia

b)Bellevue Hospital, New York

Who is Philadelphia named after?

a) In remembrance of the Philosopher Philo Judaeus
b) Named after King Ptolemy II's expedition Philadelphus
c) Named to envision "brotherly love" a literal translation of "Philadelphia" in Greek.

c) Named to envision "brotherly love" a literal translation of "Philadelphia" in Greek.

Facebook has _____ monthly active users, approximately?

a) 250 million
b) 1.5 billion
c) 5 billion
d) 2.5 billion

d) 2.5 billion

Survey

https://www.surveymonkey.com/r/prepaneldiscussions

CSV identified as a barrier for the FDA…

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

Computer

System

Validation!!!

The Industry CSV Team

Streamlined Risk-Based CSV

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

Company	Name
Johnson and Johnson	Dana Guarnaccia
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
Siemens Digital Industries	Thorsten Ruehl
Zoll Lifevest	Frank Meledandri Sr.

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

Cultural Barriers Paralyzing Industry

Streamlined Risk-Based CSV

For software not used in product, manufacturers refer to significantly more burdensome guidance (20+ years old), based on Fear of a 483, 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!"

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

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

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

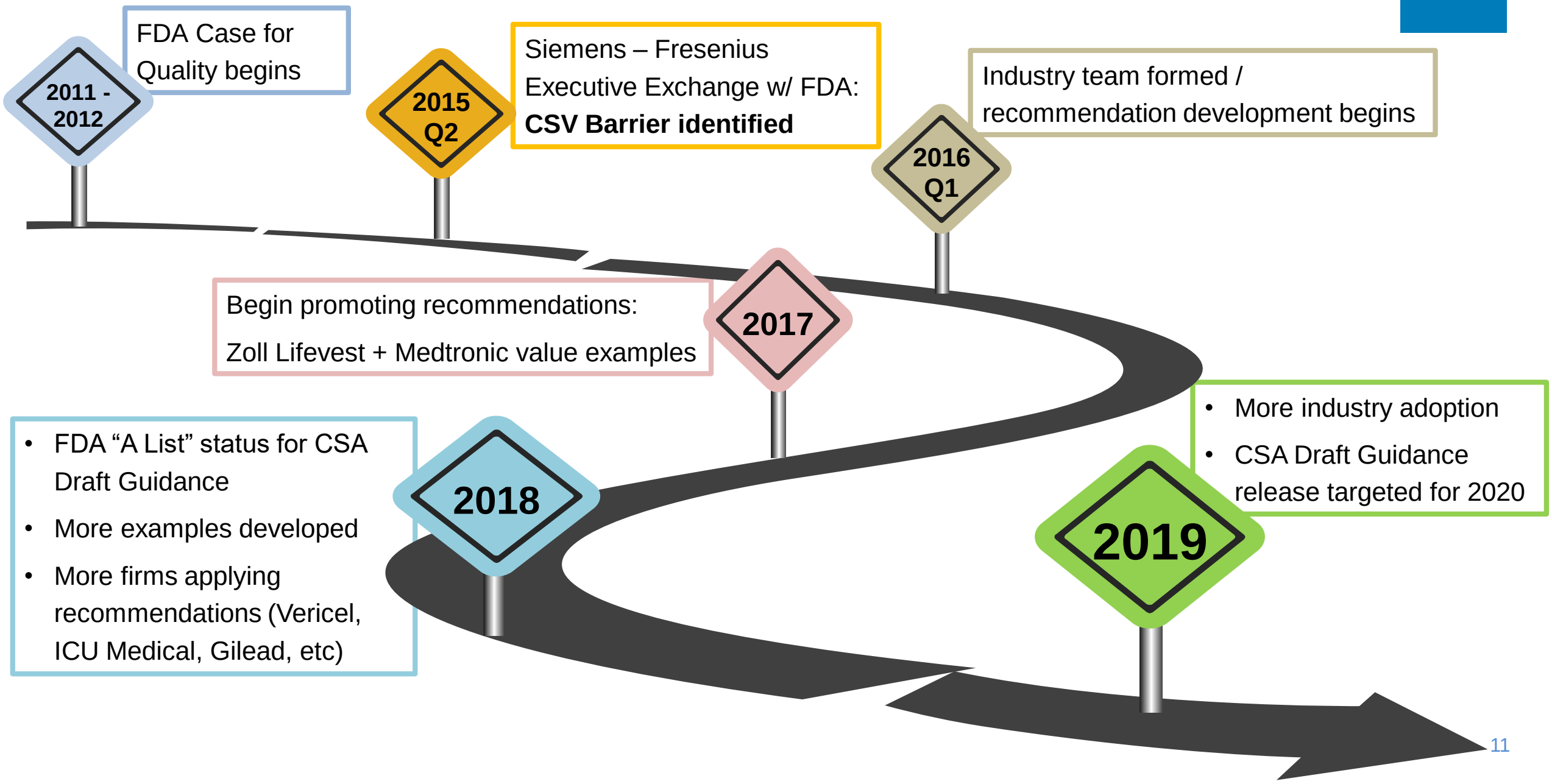
"The real pain no one discusses, is the CSV burden over the lifecycle of maintaining software."

"What If analysis not practical to maintain"

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!

Journey of FDA CSV Team



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)

FDA announcement link. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2020-fy-2020#a

The Quality System regulations allow for a manufacturer to apply a critical risk-based approach to their assurance activities. ***Establishing the intended use of the system, software, or feature is the foundation for determining the direct impact to device safety, device quality, or quality system integrity***. Furthermore, 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.

Impact to medical device ecosystems future state

All efforts to modernize and improve the whole ecosystem, rely on the adoption of technology, data systems, 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

Removing barriers to adoption, caused by the interpretation of computer system validation expectations is an essential first step. Industry wants this!

A Paradigm Shift

Channelling John Murray

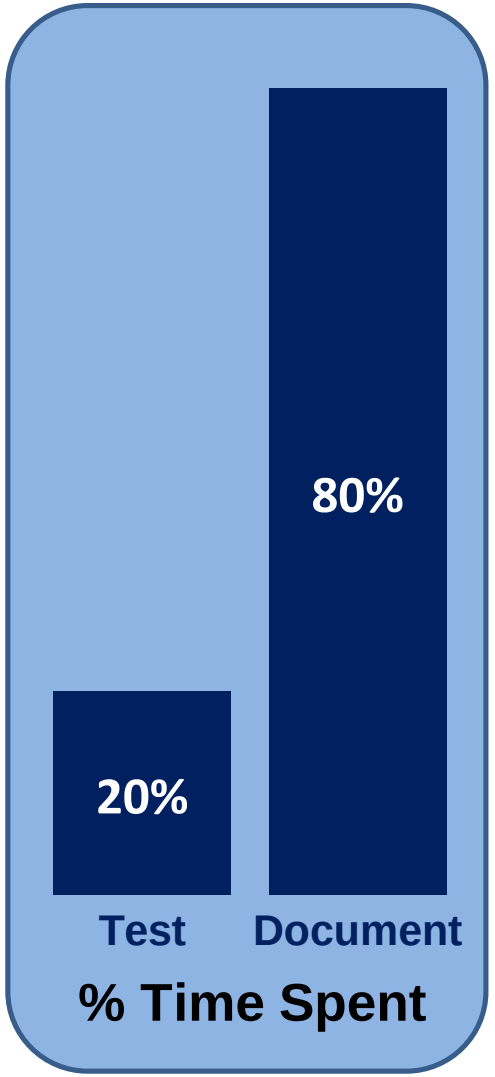
Streamlined Risk-Based CSV

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



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.

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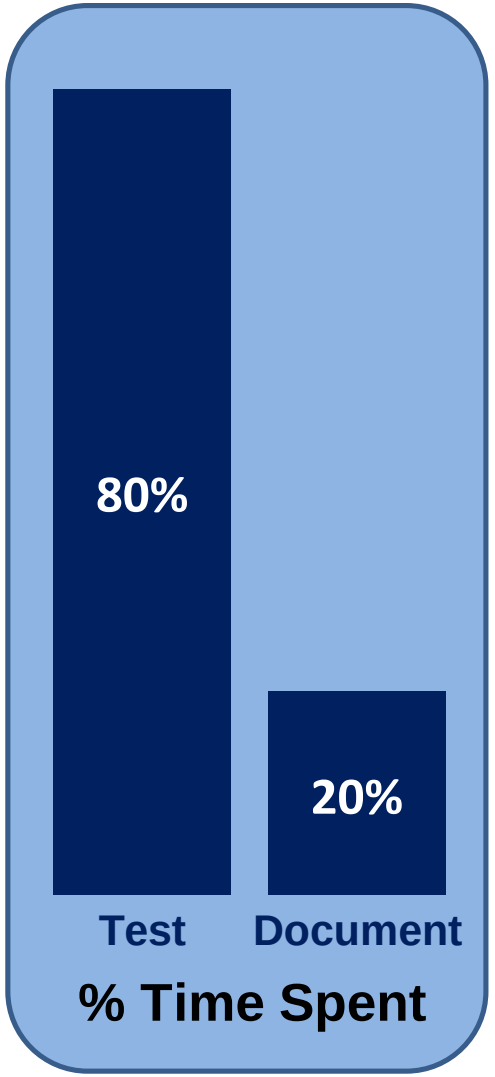

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Spreadsheet to Analyze and Graph Non-conformances

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

Test Assurance Report

- **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

Vs

- **1 page vs 25 pages**
- **1 hour vs 5 days**
- **Product quality is equivalent or better**
- **Focus on the right level of assurance on the right things, eliminate redundancy**

More value examples…

Streamlined Risk-Based CSV

COMPLIANCE group

icumedical

- 50+ GxP Computerized systems remediated using CSA
- 95% reduction in Test Script & Tester errors
- > 40% reduction in validation test cycle times
- Successful MDSAP Audit on Software Validation

Biopharma Company

- 40% reduction in validation test cycle times
- 90% reduction in Test Script & Tester errors
- 2 successful internal audits on Software Validation

VERICEL

- 90% reduction in test script issues
- > 50% reduction in validation spend & time

ConvaTec

- > 50% reduction in validation test cycle times
- 90% reduction in Test Script & Tester errors
- Successful MHRA Audit on Software Validation

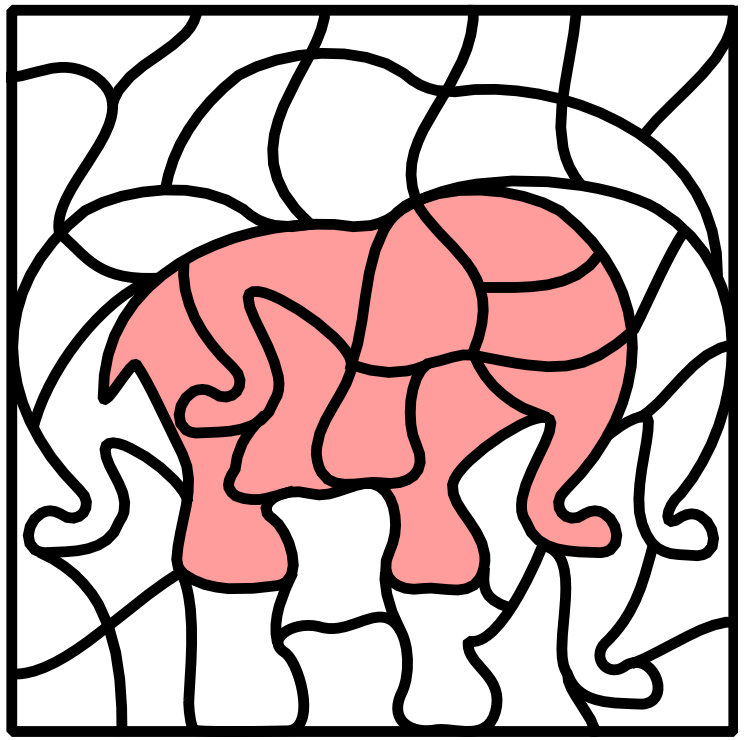
Industry Case Study – LIMS Example

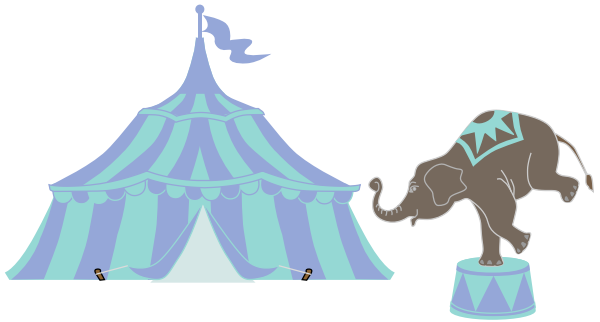
Before

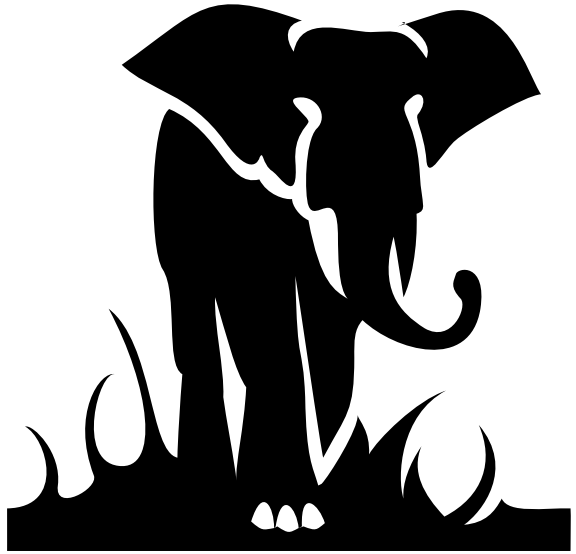
1. Functional Complexity (OOB vs Configured vs Custom) wasn't factored into Risk Rating calculation.
2. Testing not scaled or justified by Risk Ratings.
3. Focus on Scripting (documentation).
4. Heavily scripted IQ/OQ/PQ.
5. 28 test script & tester errors. 0 system errors.

After

1. Factor Functional Complexity (OOB vs Configured vs Custom) into Risk Rating calculation.
2. Scale testing per Risk Ratings of individual functions.
3. Focus on Testing.
4. 20-30% Scripted, 70% Unscripted.
5. Most test script & tester errors would've been eliminated. Will be more likely to find system errors before go-live.





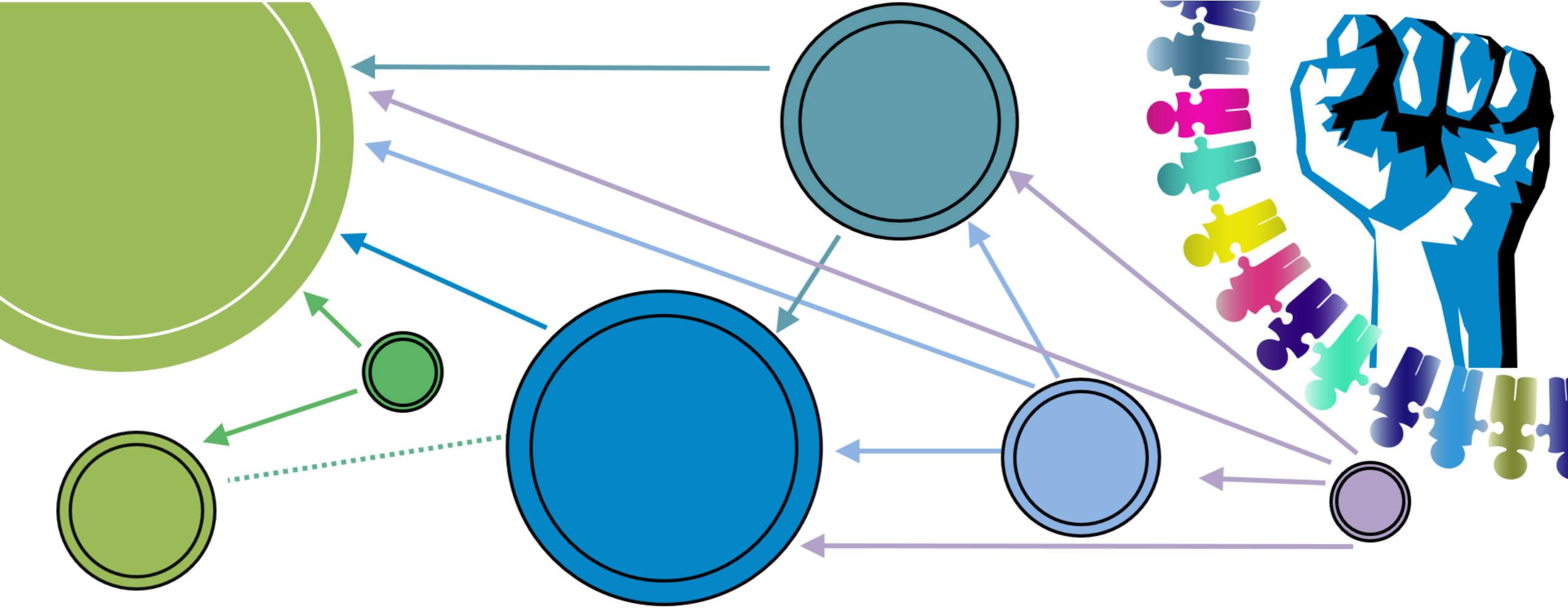


What Kind of Elephant Are You?

GILEAD

Video #1

https://www.youtube.com/watch?v=b5AWhh6MYCg



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)

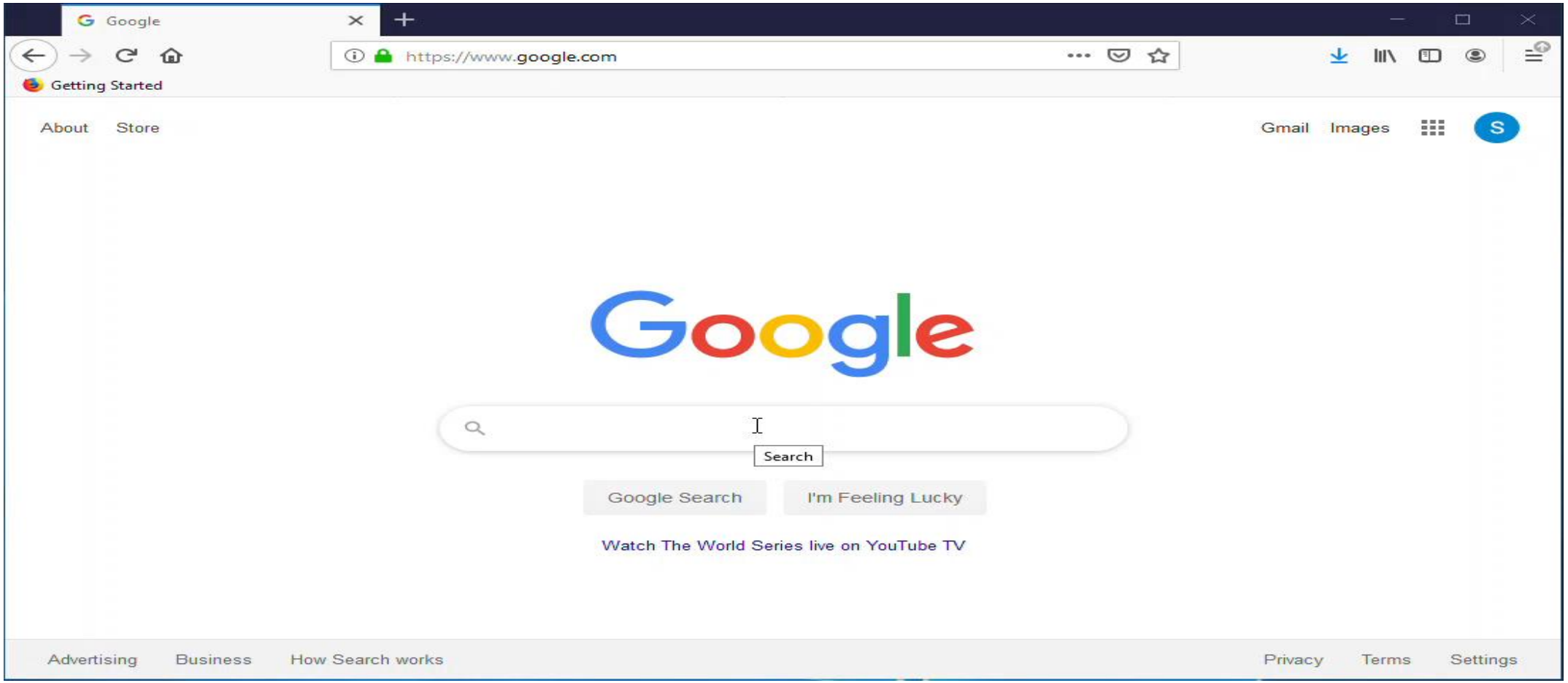
2003
- 21 CFR 11 Scope and Application (CDER, CBER, CDRH)

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

2017
- CPG 7348.810 Bioresearch Monitoring

GILEAD

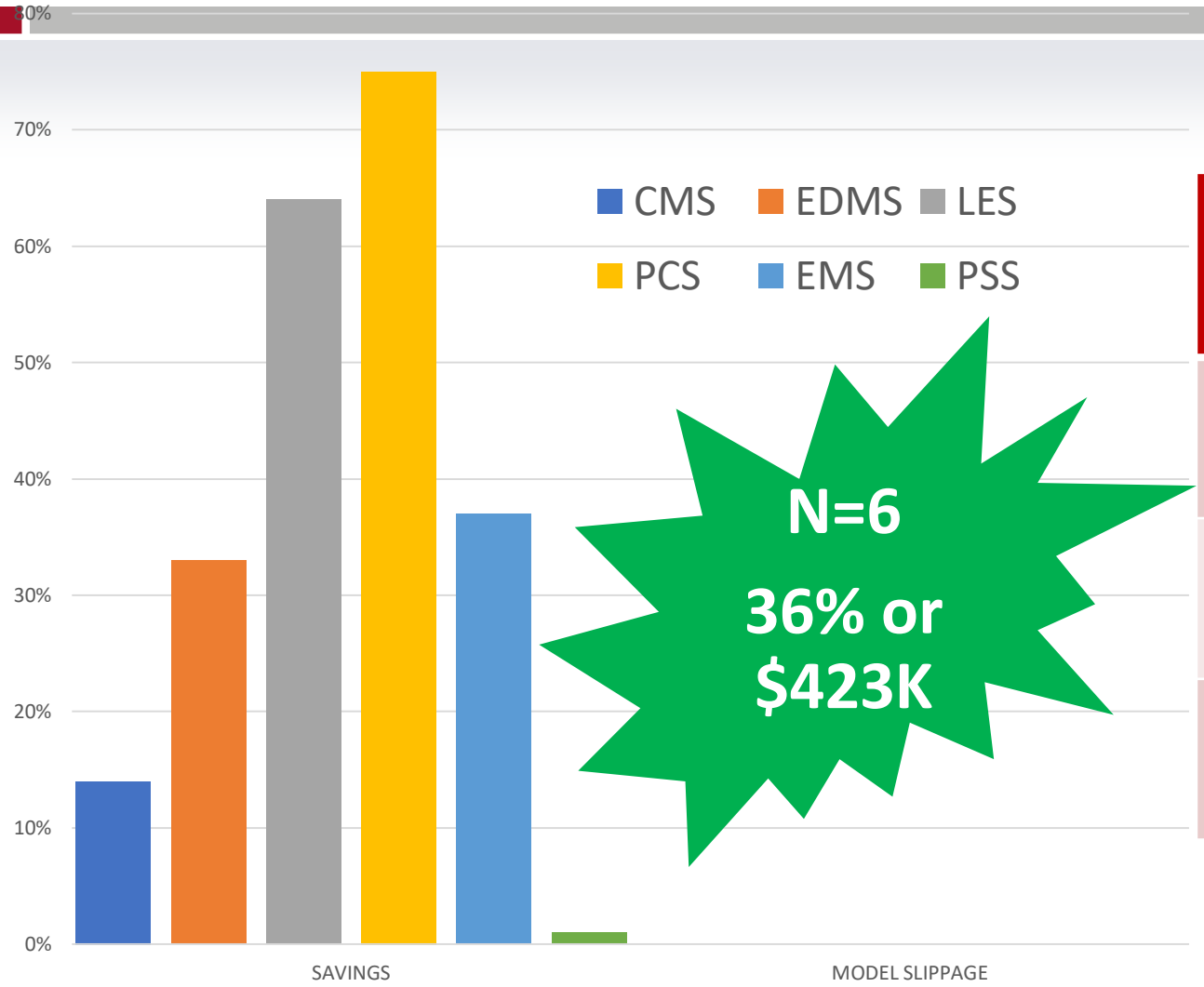
Video #2


Google
https://www.google.com
Getting Started
About
Store
Gmail
Images
S
Google
Search
Google Search
I'm Feeling Lucky
Watch The World Series live on YouTube TV
Advertising
Business
How Search works
Privacy
Terms
Settings

23

Empirical Analysis

Validation Effort Comparison of Traditional vs. New Models and Their Potential Savings



Other Techniques	Value
Leverage SQA	$12 M Est. 2017-2019 Over $6 M Actual in 2020
Continuous Compliance	Eliminates Need For Point-in-Time Validation
Build Automation	Eliminates Need For Deployment Verification

GILEAD

* Bold = favorable audit

Survey

https://www.surveymonkey.com/r/postpaneldiscussion

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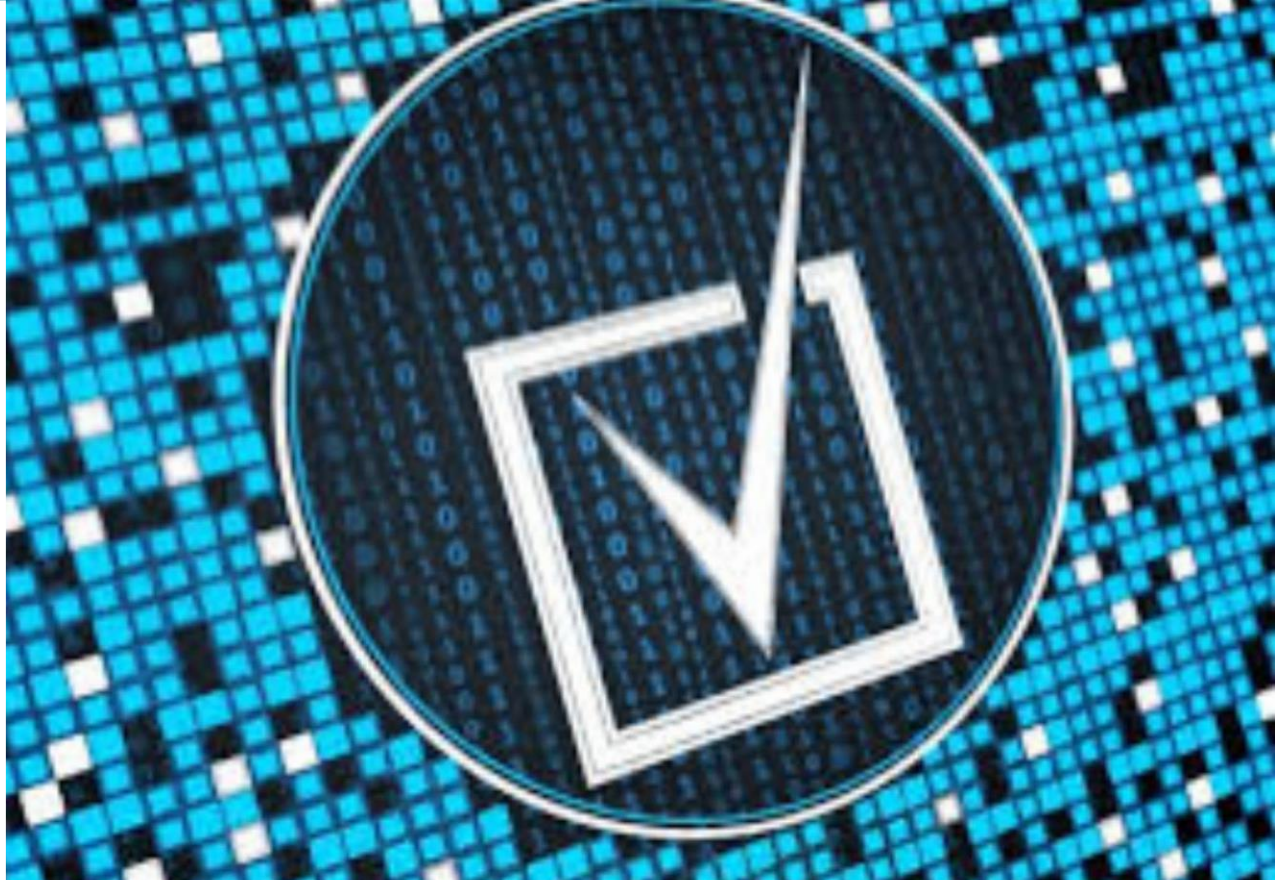
BONUS MATERIAL



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

Focus on Assurance

Shift the discussion

(Unique) Clarifications and Recommendations

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.

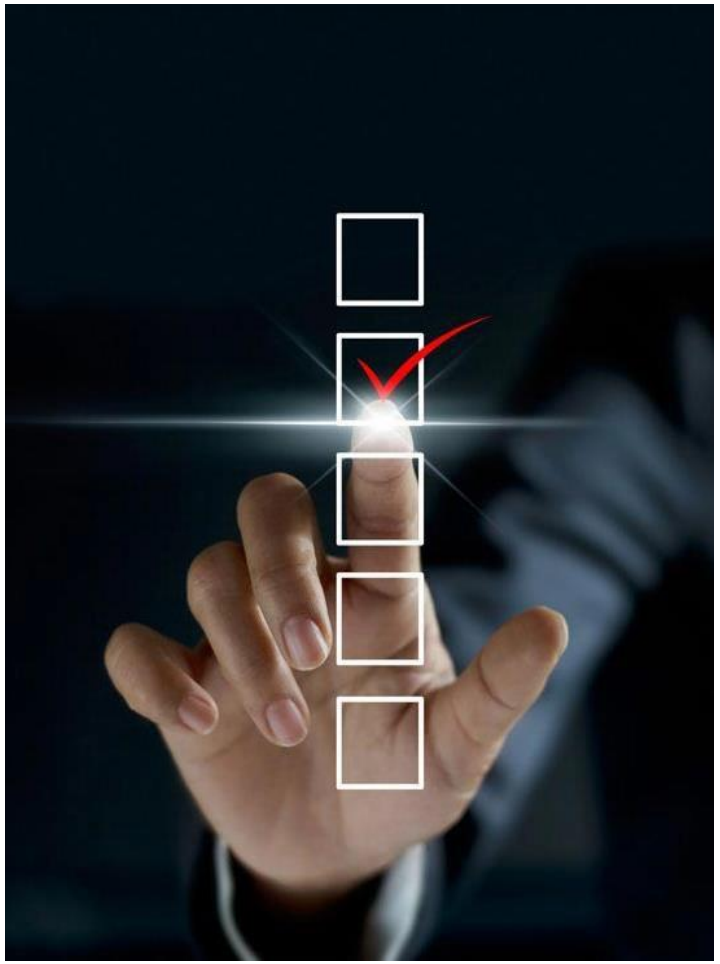
Evidence Capture Methods

- 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

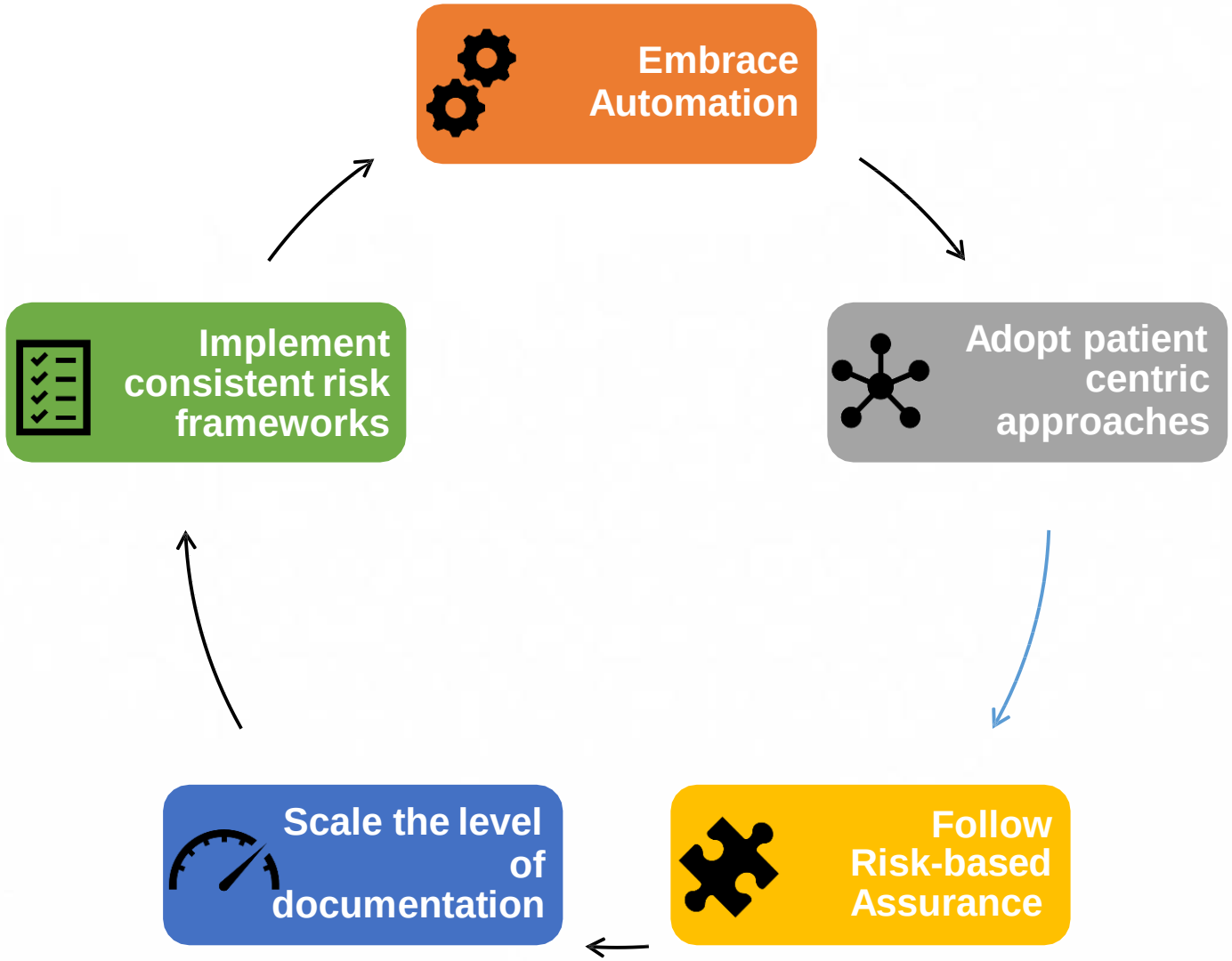
Appropriate methods and activities for software assurance



- 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

- *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

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

LifeVest®

Presented by Frank Meledandri Sr
Siemens Software – Medtronic – FDA Design Excellence Event, May 15, 2018

ZOLL.

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

System Level

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 HIGH	Change Level Risk MEDIUM	Change Level Risk LOW
• Add traceability from Requirements to Design to Test case • Test all new requirements • Execute formal regression testing	• 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	• Standard traceability Requirements to Test cases • Informal testing for IT system • Informal testing for UAT

Medtronic

*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**

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*Presented by Medtronic on March 12, 2019 at IVT Medical Device Week in Minneapolis MN

GLOBAL IT QUALITY PAIN POINTS & SOLUTIONS

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

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QUALITY BEGINS WITH ME

POLARION
USE IN MEDTRONIC NON-PRODUCT SOFTWARE

BENIFITS

- ✓ **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**

USER FRIENDLY

- Easy to adopt, use and support
- Flexible process for validated and non-validated applications/projects
- Repeatable process execution across the Global IT organization

IMPROVED DOCUMENTATION

- Central repository for living validation documentation
- Real time template updates applied to new documents
- Eliminate paper execution of methodology
- Migration of existing data (documents, QC)

TRACEABILITY END-TO-END

- Electronic signatures 21CFR part 11 compliant
- System of record for validation status
- Ability to support on-demand IT audits
- Cross-functional reporting

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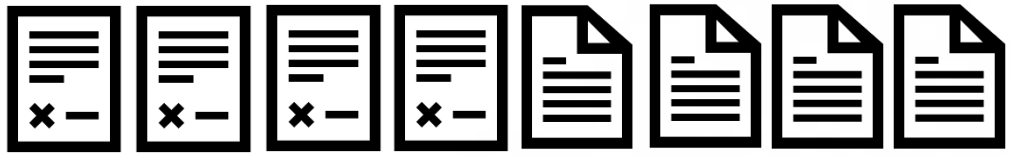
Case Study Examples – Embrace Automation – Infrastructure Qualification

COMPLIANCE group

FDA CSV Team Recommendation	• Use **electronic** data capture and record creation, vs **paper** documentation, screen shots, etc. • Leverage continuous data and information for monitoring and assurance
Success Story Brief Description	• Replaced **manual, paper based** test evidence capture with an **automated** approach. • Replaced **manual, error-prone** specification maintenance with an **automated, error-free** specification generation approach.

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

COMPLIANCE group

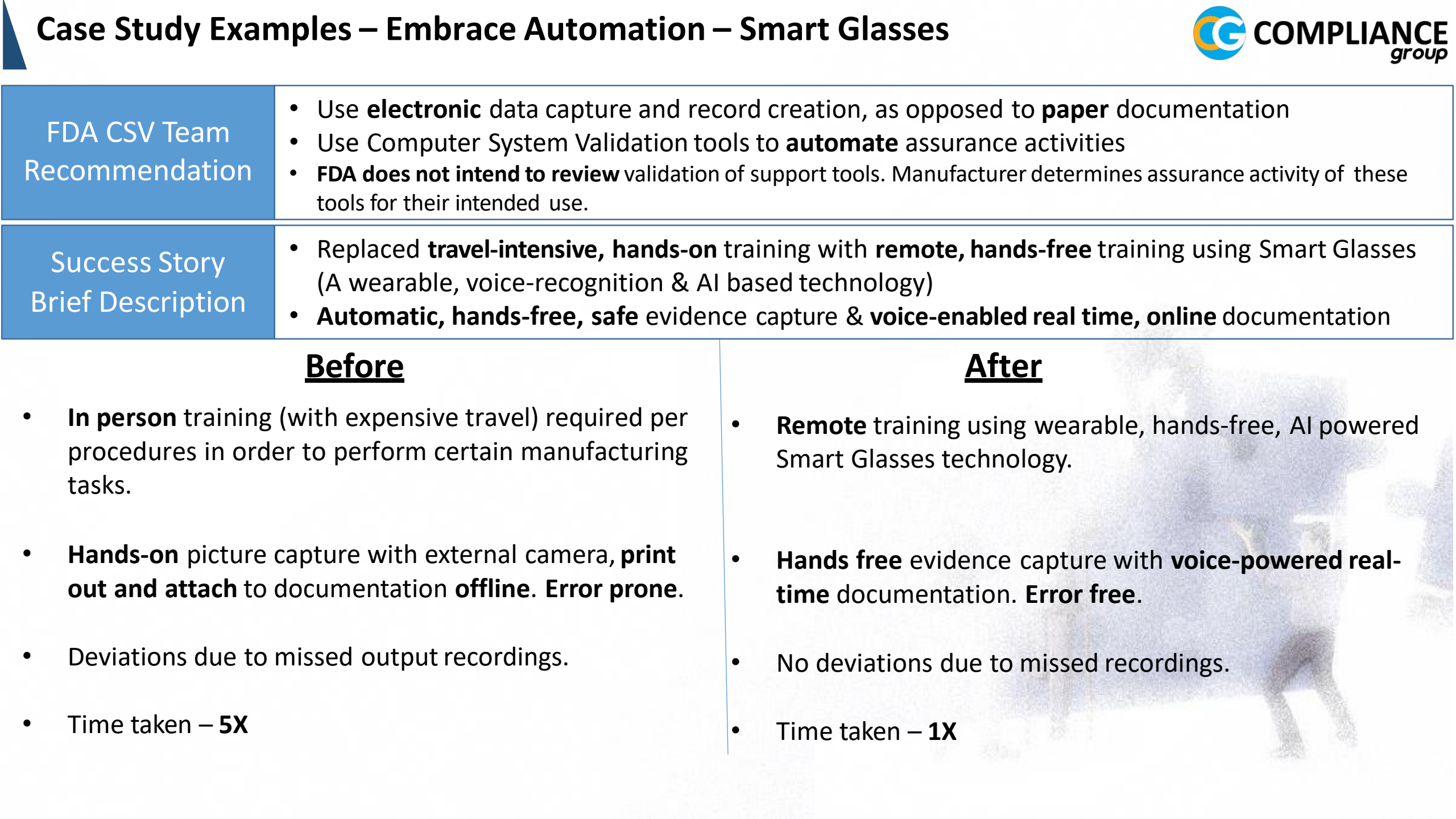
FDA CSV Team Recommendation	• Use **electronic** data capture and record creation, as opposed to **paper** documentation • Use Computer System Validation tools to **automate** assurance activities • **FDA does not intend to review** validation of support tools. Manufacturer determines assurance activity of these tools for their intended use.
Success Story Brief Description	• 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

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 patient centric risk framework across Software life-cycle – i.e. Validation, Change Management & Periodic Reviews. • Leveraged FDA CSV Team's risk assurance framework.

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.

Before

- One-size-fits-all list of validation documentation for all types of software
- Creation of documentation – not assurance
- Time consuming validation cycles

After

- Deliverables scaled (both quantity & quality) by using a risk assurance framework included in FDA CSV Team's recommendations
- Creation of "assurance" – not just documentation
- At least 25% improvement in validation cycles

MES Example

Risk	Patient/Product
	From failure, event, or consequence with potential to cause:
Low	• Minor harm to a patient.
Medium	• Significant but temporary harm or reversible damage to a patient
High	• Death, life-threatening harm, or irreversible damage to a patient.

Implementation Definitions	
Out of the Box	Feature works simply by installing the software and adding necessary master data (e.g. products, BOM, routes, etc.).
Configured	Feature is enabled through the setting of parameters without changing the code of the software
Custom	Feature requires programming or change to software code

		Implementation Method		
		Out of the Box	Configured	Custom
Patient Risk	High	3	4	5
	Medium	2	3	4
	Low	1	2	3
	None	1	1	1

Risk Rating	Assurance Activities
5	Requirement validated through robust scripted testing
4	Requirement validated through limited scripted testing
3	Requirement validated through unscripted testing
2	Requirement validated through ad-hoc testing
1	Relies on vendor audit and base-line assurance

Replacing custom MES with COTS MES.

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

Feature	Patient Risk Level	Assurance Activity	
		Custom MES	*COTS MES
Training Enforcement	Low (Product quality inspected at multiple steps in process)	**3 - Unscripted**	**1 - Vendor Audit**
Material Expiration Enforcement	Medium	**4 - Limited Scripted**	**2 - Ad Hoc**
Label Printing	High	**5 - Scripted**	**3 - Unscripted**

*Out of the Box implementation

Automated Computer System Validation Tools

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

Risk Based CSV Example: Learning Management System (LMS)

Streamlined Risk-Based CSV

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

Streamlined Risk-Based CSV

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.

Basic Assurance / Low Risk Features	Ex: Usability Features – required data entry from optional data entry, attachments of objects, system workflow, non conformance initiation.	Ad Hoc Testing 30%
Medium Risk Features	Ex: Electronic Signature Features – audit trail, meaning of signature (review, approval).	Unscripted Testing 50%
High Risk Features	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.	Scripted Testing 20%