A Paradigm Shift in Driving Improvements

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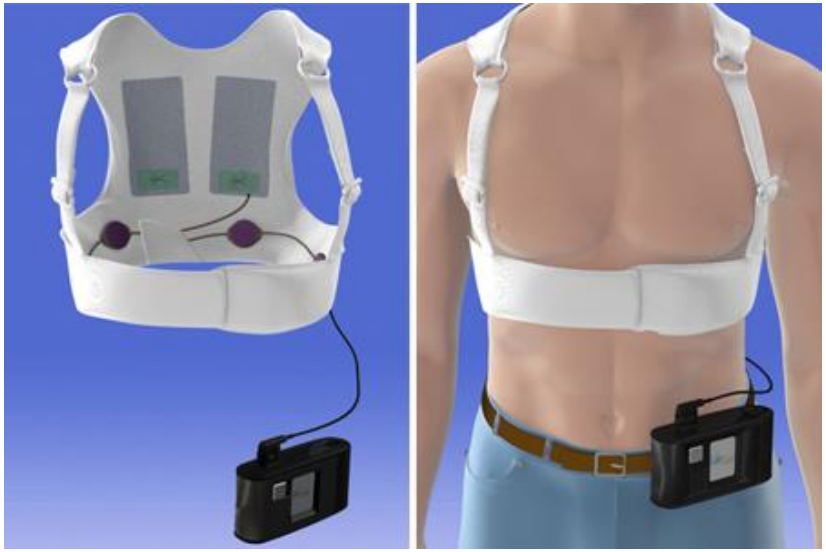
Introduction

- **Frank Meledandri** – 17 Years Experience
- **Current** – Manager, Quality Assurance Group – ZOLL LifeVest
- **ZOLL LifeVest** – The LifeVest wearable defibrillator is a treatment option for sudden cardiac arrest that offers patients advanced protection and monitoring as well as improved quality of life.



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Background

Business challenges:

- Rapid innovation and growth driving increased variability in Manufacturing
- Processes, data collection, and improvement efforts focused on delivering regulatory artifacts. Not scalable from a resource, cost, and quality culture perspective
- Regulatory challenges increased cost and time of implementing improvements and systems

Improving speed, visibility, and control

- Implementing technology to enables operational and manufacturing quality excellence
- Automate data collection, increase process and product knowledge, improve defect detection and responsiveness, error-proof and lean manufacturing process reducing non-value added inspections/verifications, etc
  - Paper reduction from 38,500 pages/week to 500 pages/week
- Modern, configurable COTS solution from established mature vendor in the industry

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A Paradigm Shift – Our CSV Story

Go Live – *Excitement*!!!

And then came the *change requests* to optimize the process…and CSV!!!

CSV Approach

- ***HEAVILY SCRIPTED***, very conservative
- Initial system testing included in CSV

Business Impact

- Long detailed "error prone" test scripts
- Large volumes of paper
- Time intensive multiple-sign off stages
- ***CSV Team always blamed for extended time lines.***

Culture Impact

- Rapid decline in overall morale surrounding system and CSV process
- Accelerated pace of change requests outpacing CSV resources
- Training becomes barrier - content/time
- High frustration levels
- Nobody wants to touch CSV, making training more difficult
- High uncertainty within CSV process / requirements
- ***My CSV Engineer Quit!***

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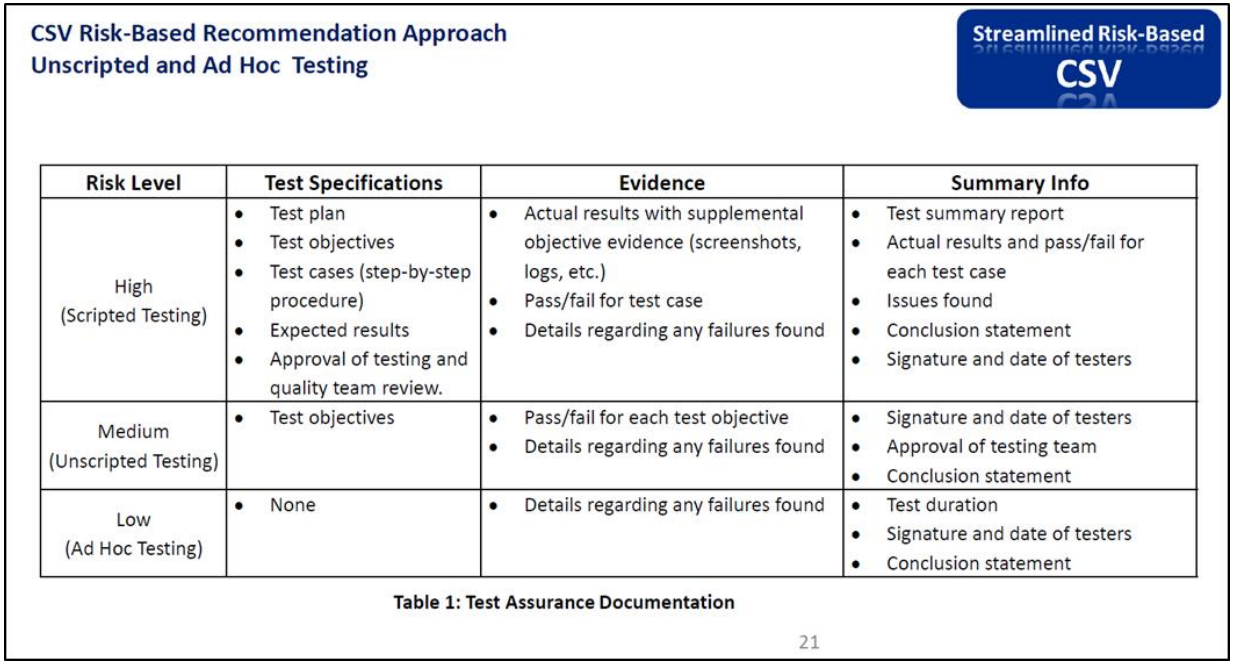
A Paradigm Shift – The Awakening

Then we learned about the FDA – Industry CSV team's "risk-based" approaches

A Paradigm Shift…and a Life Saver!

- ***Vendor Qualification***
- Analytics and Reporting
- ***Unscripted / Ad-Hoc Testing***
- Automated CSV Risk Management



CSV Risk-Based Recommendation Approach
Unscripted and Ad Hoc Testing

Streamlined Risk-Based CSV

Risk Level	Test Specifications	Evidence	Summary Info
High (Scripted Testing)	• Test plan • Test objectives • Test cases (step-by-step procedure) • Expected results • Approval of testing and quality team review.	• Actual results with supplemental objective evidence (screenshots, logs, etc.) • Pass/fail for test case • Details regarding any failures found	• Test summary report • Actual results and pass/fail for each test case • Issues found • Conclusion statement • Signature and date of testers
Medium (Unscripted Testing)	• Test objectives	• Pass/fail for each test objective • Details regarding any failures found	• Signature and date of testers • Approval of testing team • Conclusion statement
Low (Ad Hoc Testing)	• None	• Details regarding any failures found	• Test duration • Signature and date of testers • Conclusion statement

Table 1: Test Assurance Documentation

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*Presented by FDA-Industry CSV team at Siemens PLM-Medtronic June 28 2017 Intelligent Design Control event

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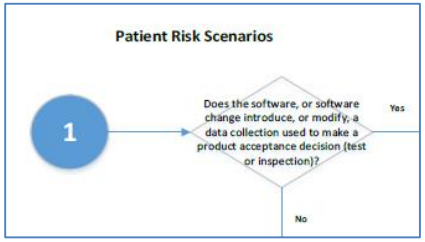
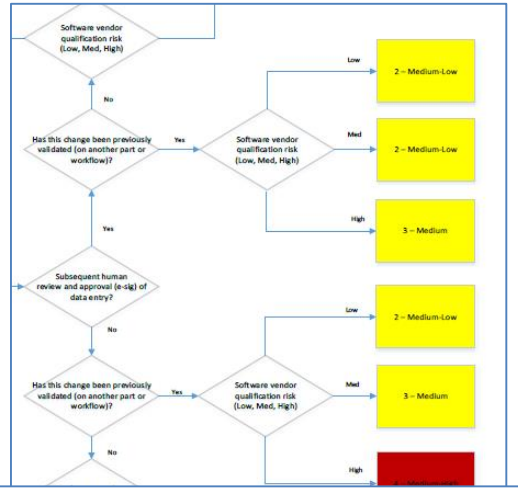
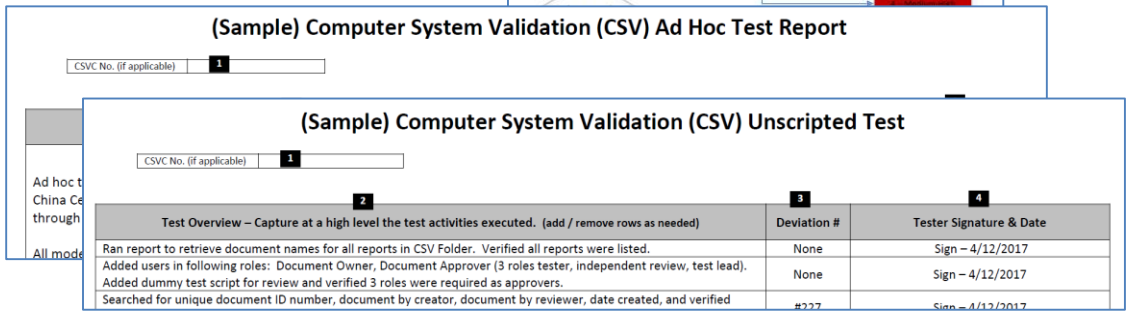
A Paradigm Shift – The Change

How to ensure consistent selection of the correct Test Method?

- ***Level One Questions***
  - Software or Software Change based on *Patient Risk*
  - Software or Software Change based on *Regulatory Risk*
- ***Decision Tree Flow Chart Risk Based Algorithms***
- ***Leveraging pilot CSV recommendations***







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A Paradigm Shift – The Impact

Metric	Pre	Post	Impact
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
Validation System Change Backlog (Camstar & Epicor)	90 changes in backlog (Extreme Frustration / low morale)	0 Changes in backlog!	• High morale • More value from technology • Higher quality and productivity
Camstar SU13 Upgrade Timeline	Feb ‘18	Nov ‘17	• Utilize system improvement upgrades
CSV 589 – Sublevel monitor work flow configuration update	18 days	3 days	• 84% reduction.
CSV 501 – ECG BOM Filter Improvements	Modeled Apr ‘17 Scheduled Oct ’17 Due to resources and backlog	Aug ’17 – Performed Validation 1 day Validation	• More real time implementation of system improvements.

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A Paradigm Shift – The Conclusion

- Be open to FDA collaboration
  - FDA and Industry collaboration is a game changer and *creates great optimism for efficiency improvements*!

- Change the Culture
  - Push back on historical misperceptions as you drive changes.
  - Do NOT let misperceptions *hamper creating value with improvement and innovation!*
  - Simpler, streamlined approaches will
    - Allow faster system improvements
    - Enable easier training to the process
    - Help recruit and onboard better talent
    - Increase Team Morale
    - Ensure consistent processes focused on doing what is best for patient and business

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