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.
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
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!*
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

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Test Specifications</th>
<th>Evidence</th>
<th>Summary Info</th>
</tr>
</thead>
</table>
| 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

*Presented by FDA-Industry CSV team at Siemens PLM-Medtronic June 28 2017 Intelligent Design Control event*
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**
# A Paradigm Shift – The Impact

<table>
<thead>
<tr>
<th>Metric</th>
<th>Pre</th>
<th>Post</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Validation Time</td>
<td>38 day Average</td>
<td>7 day Average</td>
<td>83% reduction</td>
</tr>
<tr>
<td>Service Defect Tracking (Camstar customization)</td>
<td>PQ = 22 runs, 35 days</td>
<td>PQ = 1 run, 3 days</td>
<td>91% reduction</td>
</tr>
</tbody>
</table>
| 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 workflow 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. |
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