Resolving problems using a FRACAS* - driven by CMMS data with a Power BI dashboard

*Failure Reporting and Corrective Action System
AGENDA

1. Presenters/Company Information
2. Reliability Team DMAIC Model
3. M.O.R.E. Team
4. Problem Description
5. Define
   - Major Losses
   - CMMS Data
6. Measure (before & after)
   - Shift Notes
   - CMMS Data
7. Analyze/Implement/Control
   - Power BI Dashboard
8. Results/Summary
9. Questions??
Presenters
Holly Springs, NC Reliability Team

Michael Cook
Principal Reliability Engineer

M.S. in Maintenance Management & Reliability Eng.
University of Tennessee/Monash University
B.S. Mechanical Engineering
University of Connecticut

25+ years of reliability leadership experience in the U.S., Mexico and Canada implementing Predictive Maintenance and Reliability Engineering programs in the power, paper and pharmaceutical industries.

Vibration Institute Level IV Vibration Analyst & 2x program of the year award - Uptime Magazine.

Sukhjinder Singh
Maintenance and Reliability Lead

Maintenance and Reliability Lead at CSL Seqirus’ Holly Springs, NC, cell-based influenza vaccines manufacturing facility.

28+ years Plant Maintenance experience in Electrical, Instrumentation, Calibration, and Reliability field.

13+ years working at CSL Seqirus in Instrumentation, Calibration and Reliability.
About CSL Seqirus Holly Springs, NC

The site is largest cell-based influenza vaccine manufacturing site in the world:
- First-of-its-kind in the U.S.
- Purpose-built in 2009 through a public-private partnership with BARDA

Established cell-based technology as a highly scalable method for seasonal and pandemic influenza vaccine production

The site is a strategic site for public health:
- Seasonal flu operations
- Pandemic Preparedness
- Next generation flu
Facts & Figures

HIGHLIGHTS

• Capacity to supply > 150 million doses of pandemic vaccine within 6 months of a pandemic declaration
• Produces seasonal, pre-pandemic and pandemic influenza vaccines and MF59® Adjuvant
• State-of-the-art product development capability (cell culture & mRNA)

FACILITY

• Highly automated end-to-end manufacturing
• >1100 employees (includes contingent workers)
• Recently completed a $156M expansion, bringing the facility to 664,000 square feet
Influenza Cell-Based Vaccine Production
Reliability Team
Values, Vision & Mission

**Values**: Use risk based Reliability processes to meet production goals

**Vision**: Change from a reactive organization to a proactive one

**Mission**: To work proactively in interdepartmental teams to facilitate change & meet goals
DMAIC Model

FRACAS is a mid-level tool

<table>
<thead>
<tr>
<th></th>
<th>High Level Site Criticality</th>
<th>Mid Level Sub-Component</th>
<th>Focus Level Root Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define</td>
<td>Define major systems</td>
<td>Define component &amp; failure modes for critical systems</td>
<td>Define threshold for all major indicators: delays, downtime</td>
</tr>
<tr>
<td>Measure</td>
<td>Measure risk in each major system</td>
<td>Quantify downtime for each failure mode</td>
<td>Measure and report batch delays, corrective Maintenance hours</td>
</tr>
<tr>
<td>Analyze</td>
<td>Identify high risk systems</td>
<td>Determine which failure modes to improve based on downtime</td>
<td>Analyze all root causes focusing on those that exceed thresholds</td>
</tr>
<tr>
<td>Improve</td>
<td>Make improvements to high risk systems</td>
<td>Make improvements to individual failure modes to reduce risk</td>
<td>Develop corrective actions for problems that exceed thresholds</td>
</tr>
<tr>
<td>Control</td>
<td>Monitor results in next seasonal campaign</td>
<td>Monitor results of improvements for each failure mode</td>
<td>Monitor completion of corrective actions by Root Cause group</td>
</tr>
</tbody>
</table>

Driven by Our Promise
CSL SEQIRUS M.O.R.E. Team
Reliability is a “Conduit for Information”

Maintenance
Operations
Reliability
Engineering

Operational Data Improvements

- Work Orders
- Maintenance Shift Notes

- Analysis Results based on Shift/Maint. Notes
- Planned Projects

Operations
Shift Notes

Maintenance

Operations

Reliability

Engineering
“DEFINE” – Goals & Problem Description

Production Constraints

Over the past 4 seasons as demand has increased, losses in availability, quality, or throughput put us at a greater risk to not meet a 20 week production calendar

Increased Demand for Flu Vaccine

Doubled the first 4 years of production in the last 2 years
“DEFINE” – 2019 WO Count
SAP Data 2019 Fill/Pack (Line 1)
Seasonal (May-Sept)
“DEFINE” - Problem Description – “Why Now”?
Fill/Pack (Line 1) Seasonal (May-Sept) Downtime 2019-2022

- 2019 - 1063 hrs.
- 2020 - 981 hrs.
- 2021 - 671 hrs.
- 2022 - 1092 hrs.

(107 hrs.)
(188 hrs.)
(185 hrs.)
(204 hrs.)

Filler downtime hours
(#1 cause of DT in 2022)
“DEFINE” - 6 Major Losses - New in 2022

Aim/Goal: Impact to Production Schedule

- **Primary Drivers**
  - Unplanned Stops (24%)
  - Planned Stops (11%)
  - Small Stops (~5%)
  - Slow Cycles (~5%)
  - Production Defects (~2%)
  - Startup Defects (~2%)

- **Secondary Drivers**
  - Equipment Failures
  - Set-ups
  - Adjustments
  - Minor Stops
  - Reduced Speeds
  - Filling Rejects
  - Packaging Rejects
  - Write-Offs

- **Tertiary Drivers**
  - Reduce MTBF
  - Improve MTTR
  - OE Management
  - Reduce Maintenance related root causes
  - Production Monitoring System (not in place)
  - OE and Data Historian
  - Filling MORE team
  - Packaging MORE Team
  - Quality/Bulk Teams

**Impact to Production Schedule**

- **Availability Losses**
- **Performance Losses**
- **Quality Losses**

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Impact

Implementation

Detectability
“DEFINE” - 6 Major Losses – Litmus Test

- Production
- Write-Offs
- Set-ups
- Filling Rejects
- Small Stops
- Speed Losses
- Equipment Failures
- Packaging Rejects
- Adjustments

OEE Estimate

- Equipment Failures: 24%
- 3.50%
- 5%
- 5%
- 5%
- 5%
- 2%
- 2%
- 11%
- 53%
### “MEASURE” – Downtime Data

Starts with “Manufacturing Shift Notes”

<table>
<thead>
<tr>
<th>Incident Date</th>
<th>Duration of DT</th>
<th>Major Component</th>
<th>Symptom/Reject</th>
<th>Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SHIFT NOTES**

- Incident Date
- Duration of DT
- Major Component
- Symptom/Reject
- Notification

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**DOWNTIME EVENT:**

- Incident Date
- Duration of DT
- Major Component
- Symptom/Reject
- Notification
“MEASURE” – M.O.R.E. Team Data Collection

- Downtime reporting accuracy
- Omitted data
- Work Order reporting accuracy
- Incorrect FLOC (20%+ inaccuracy)
- Engineering interpretation accuracy
- Maintenance conclusion
“ANALYZE” – Historical Trend

Pooled downtime data is hard to interpret using standard output
“ANALYZE” – Shift Data

Data helps identify Operational variance between the 4x12hr. shifts
“ANALYZE” – Power BI SME Process

STEP 1 – Major Component Level Review

- Data auto sorted by duration by major component
- Can be filtered by week, month or season
STEP 2 - Drilling down to Component Level

Data drilling down for:
- Work Order Details
- Historical Trend
- Failure Modes
"ANALYZE"

STEP 3 - Historical Chart by Major Component (2022)

Chart Usage:
• Chronic vs. Sporadic
• Increasing/Decreasing
• In-season/Out of season
"ANALYZE" – Merging Data

STEP 4 - Reviewing merging operation shift logs with CMMS work order data

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Equipment</th>
<th>Component</th>
<th>Description</th>
<th>Shift Notes</th>
<th>SAP Work Order</th>
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</thead>
<tbody>
<tr>
<td>06/06/20</td>
<td>22</td>
<td>Labeler1</td>
<td>Infeed</td>
<td>Overload infeed arm not feeding properly (not clear on feed arm description)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>06/07/20</td>
<td>22</td>
<td>Labeler1</td>
<td>Infeed</td>
<td>T: Alarm #1, Maintenance #104035, Sensor #1, Contact load, 3.5 hours.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Downtime Data**
- Incident Date
- Duration of DT
- Major Component
- Symptom/Reject
- Notification

**Work Order Data**
- Component/Sub Comp
- As found/As left
- Actions taken
- Duration

**SHIFT NOTES**

**DOWNTIME EVENT:**
- Incident Date
- Duration of DT
- Major Component
- Symptom/Reject
- Notification

**MAINTENANCE WO:**
- Component/Sub Comp
- As found/As left
- Actions taken
- Duration
“ANALYZE” - Classification

STEP 5 – Assigning Major Component, Sub-Component and Correction Codes

SHIFT NOTES-weekly

SME/ENGINEER:
- Component/Sub Comp
- Correction Code
- Actions/Status

INSPPECT_PACK
- ACCUMULATOR
- SEIDENADER_DENESTER
- SEIDENADER_RENESTER
- GRONINGER_DENESTER
- BREVETTI_AV
- SEIDENADER_AV
- TUB_TRACKING
- LABELER_1
- LABELER_2
- FARGO

FILLING
- DEBAGGER
- EBEAM
- ISOLATOR
- DELIDDER
- FILLER
- DOCKING_STATION
- PATERNOSTER
- ACCUMULATOR

CARTONER
- BUNDLER
- CASEPACKER
- PALLELTIZER
- OPTEL_LM
- OPTEL_LABLELER_PP
- OPTEL_CARTONER_PP
- OPTEL_BUNDLER_PP
- OPTEL_CASEPACKER_PP
- OPTEL_PALLELTIZER_PP

CORRECTION
- REPLACE
- REPAIR
- CLEAN
- CALIBRATE
- ADJUST
- RESET

OE → R → E → O

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CSL Seqirus
“ANALYZE” – Power BI

STEP 5 – Historical chart inlay function

- Differentiate between chronic and sporadic problems
- Identify what items have not yet been classified
“ANALYZE” - Classification

STEP 6 - Engineering Actions, Status

SHIFT NOTES-weekly

SME/ENGINEER:
- Component/Sub Comp
- Correction Code
- Actions/Status

ACTION
- No Action
  - Status: CLOSED
- Parking Lot
  - Status: OPEN
- Root Cause
  - Status: OPEN

CLOSED
OPEN
OPEN

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“IMPLEMENT” - Action Investigations

FMEA’s, RCFA’s, Diagnostic Tools

Possible Outcomes
• Corrective Work Order
• PM Scope Revision
• Spare Parts Review
• Engineering Project
• Inspection/Diagnostic
• Training Ops/Maint/Eng
"CONTROL"

Managing Open and Closed Action Items

- Display progress report
- Display risk based progress report
“CONTROL”

Function to roll-up all component categories

• Set a cut-off line by component hours or open hours by component?
“CONTROL” - Root Causes/Corrective Action Tendencies

- Parts Changing
- Long Duration WO’s
- Re-Worked WO’s
- Delayed PM’s
- Constant Resets
- Vendor Parts Obsolete
- Delayed Turnarounds

Root Cause

- Training Shortfall
- Spare Parts Mgmt.
- Vendor Mgmt.
- Operational Spec
- Automation Issues
- PM/PdM Scope/Exec

MTTR > expected

MTBF < expected
### Habitual Overdue WO’s can lead to premature failures

#### “CONTROL” – Proactive Measures

<table>
<thead>
<tr>
<th>WO’s</th>
<th>Craft</th>
<th>ABC Indic.</th>
<th>Order Type</th>
<th>Equipment ID</th>
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<tr>
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<td>QCAST</td>
<td>1</td>
<td>YQM6</td>
<td>269547-SSSEAS</td>
<td>36M EVALUATE METHOD SOP 269547 260119</td>
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<tr>
<td>4096583</td>
<td>QCAST</td>
<td>1</td>
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<td>278855-NAFRES</td>
<td>36M EVALUATE METHOD NEURAMINID</td>
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<tr>
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<td>307963-FCCP800</td>
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<tr>
<td>4160866</td>
<td>WHSE</td>
<td>4</td>
<td>YQM6</td>
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<td>4180939</td>
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<td>2</td>
<td>YQM6</td>
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<td>4204379</td>
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<td>7</td>
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<td>05-CM-600003</td>
<td>06M RETROSPECTIVE REVIEW OSMMETER</td>
<td>12/30/22</td>
</tr>
</tbody>
</table>
“CONTROL”

Assigning Limits for Future Seasons by Component or Line or Suite

<table>
<thead>
<tr>
<th></th>
<th>Inspection</th>
<th>Labeler #1</th>
<th>Labeler #2</th>
<th>Cartoner</th>
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<tr>
<td>2020</td>
<td>99</td>
<td>44.5</td>
<td>80.5</td>
<td>57</td>
</tr>
<tr>
<td>2021</td>
<td>42.5</td>
<td>92</td>
<td>72</td>
<td>34.6</td>
</tr>
<tr>
<td>2022</td>
<td>65</td>
<td>127</td>
<td>34</td>
<td>185</td>
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<tr>
<td>Average</td>
<td>68.8</td>
<td>87.8</td>
<td>62.2</td>
<td>92.2</td>
</tr>
<tr>
<td>Weekly</td>
<td>3.4</td>
<td>4.4</td>
<td>3.1</td>
<td>4.6</td>
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</tbody>
</table>
Results

Lessons Learned

• Reductions were seen in the Southern Hemisphere as a result of Northern Hemisphere actions taken

• Outlier - Inspection machine had an unusual event in Southern Hemisphere season – Root Cause underway but the current Power BI report was not ideal in identifying the issue back to its likely initiation date

• Goals set for lines, areas and components
  • Action triggers
  • Total reduction goal for 2023 NH
Summary

Lessons Learned

• Incoming data does not need to be perfect, but the bigger the event the greater the need for accurate details

• Limiting the actionable items to >60 minutes from shift notes eliminates 40% of all downtime events and reduces the actual downtime total by 25%

• Data will need to be updated weekly to avoid having small problems becoming large ones over a 20 week season
Thank You / Questions?
“ANALYZE” – Shift Data

Data helps identify Operational variance between the 4x12hr. shifts
“ANALYZE”

- Bad data entry
  - Double data entry from upstream/downstream
  - Inaccurate data entry
  - Too much info entered by D shift
  - Not enough info entered by other shifts

- More thorough data entry
  - Not familiar with processes and procedures

- Job skill issue
  - Job skill issue previous shift (?) (see above)

- Carry over DT from previous shift

Difference between shift hours

Downtime data entry training

Skills training

New Employees
Existing Employees
“ANALYZSE” - Root Causes

Equipment Failure
- Reduce MTBF
- Improve MTTR

Set-ups
- Opex Management
- Reduce Maintenance related root causes

Adjustments
- Production Monitoring System (not in place)
- Pi/Opex Management

Minor Stops

Reduced Speeds

Filling Rejects
- Filling MORE team

Packaging Rejects
- Packaging MORE Team

Write-Offs
- Quality/Bulk Teams

Primary Root Cause

Secondary Root Cause

Driven by Our Promise

Maintenance Causes
- Reduce MTBF
- Improve MTTR

Operations Causes
- Reduce Maintenance related root causes

Reliability Causes
- Production Monitoring System (not in place)
- Pi/Opex Management

Engineering Causes
- Filling MORE team
- Packaging MORE Team
- Quality/Bulk Teams

CSL Seqirus