



Healthcare Performance Improvement

Marek Sturek

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Welcome!





Agenda

1

My journey into Healthcare

2

A brief overview of my Healthcare work

3

Connection between mind & heart, body & soul

4

Some practical examples

5

What can I do today and how to overcome obstacles



My journey

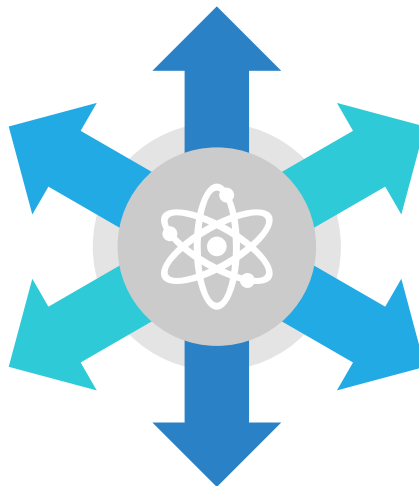
into Healthcare

Crossroad



Spojená škola Tvrdošín

"Neučíme sa pre školu, ale pre život."





A brief overview

Healthcare work

Timeline



YKHC

Bethel, Alaska



HNŠP Trstena

Trstena, Slovakia



UPOL

Olomouc, Czechia

2007

Medtronic

Fort Worth, Texas



2014

2015

YVFWC

Yakima, Washington



2019

2020

SWHR

Dallas, Texas



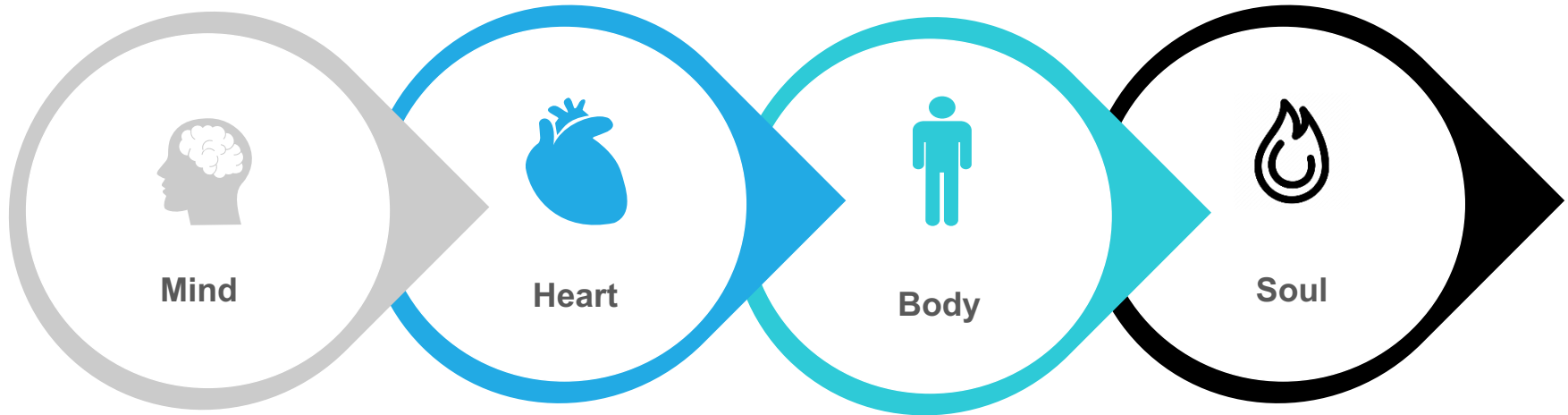
2021



Connection between

mind and heart, body and soul

Holistic approach





Practical examples

work assignments

Reactive work assignments | 1/2



Supplier Quality > Nonconformance Communication

| NONCONFORMANCE REPORT | | | | | | | | | |
|-----------------------|-----|-----------------|---------------------------------|---------|--------|--------|--------|--------|--------|
| NCR No. 11-1370 | | | | | | | | | |
| Item | Qty | Part | Product/Process/Description | Problem | Defect | Defect | Defect | Defect | Defect |
| 1 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 2 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 3 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 4 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 5 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 6 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 7 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 8 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 9 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 10 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |

| NCR 11-1393 | |
|---|--|
| <p>Conforming sample</p> <p>Description: PIN 120-089-3 Rev A clean and free of defects</p> | <p>Non-conforming sample</p> <p>Description: PIN 120-089-3 Rev A with mark/mudgels on surface</p> |

| NONCONFORMANCE REPORT | | | | | | | | | |
|-----------------------|-----|-----------------|---------------------------------|---------|--------|--------|--------|--------|--------|
| NCR No. 11-1391 | | | | | | | | | |
| Item | Qty | Part | Product/Process/Description | Problem | Defect | Defect | Defect | Defect | Defect |
| 1 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 2 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 3 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 4 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 5 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 6 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 7 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 8 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 9 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 10 | 1 | 120-089-3 Rev A | Pin A clean and free of defects | Defect | Defect | Defect | Defect | Defect | Defect |

| ZEISS Calypso | | | | | |
|---------------|-----------------|------|----------|----------|----------|
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |
| Part | 120-089-3 Rev A | Date | 10/25/06 | Operator | 10/25/06 |

| NONCONFORMANCE REPORT | | | | | | | | | |
|-----------------------|-----|------------------|-------------------------------------|---------|--------|--------|--------|--------|--------|
| NCR No. 11-1372 | | | | | | | | | |
| Item | Qty | Part | Product/Process/Description | Problem | Defect | Defect | Defect | Defect | Defect |
| 1 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 2 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 3 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 4 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 5 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 6 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 7 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 8 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 9 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |
| 10 | 1 | 311-028-04 Rev D | Pin D complete and clear of defects | Defect | Defect | Defect | Defect | Defect | Defect |

| NCR 11-1372 | |
|--|---|
| <p>Conforming sample</p> <p>Description: PIN 311-028-04 Rev D complete and clear of defects</p> | <p>Non-conforming sample</p> <p>Description: PIN 311-028-04 Rev D with end of tang cut off</p> |

CORRECTIVE ACTION REPORT (CAR) FORM

CAR No.: CAR 06-0092
☒ CA ☐ PA

| Initiation/Background Information (CAPA Coordinator / Owner) | | | |
|---|--|--|----------|
| Product Description / Quality System | Part #100-580-4 (Length Dimension) for | CAR Initiation Date | 10/11/06 |
| CAR Source | | Initial Risk Assessment | |
| <input type="checkbox"/> Management Review Meeting <input checked="" type="checkbox"/> Quality Review Board (QRB) <input type="checkbox"/> Complaint No. <input type="checkbox"/> NCR No. | | <input type="checkbox"/> CAPA System Review <input type="checkbox"/> Investigation (Inv. No.) <input type="checkbox"/> Department Management <input type="checkbox"/> Other: | |
| RAW #: NA- (Attach copy of risk assessment) | | <input type="checkbox"/> R1 <input type="checkbox"/> R2 <input type="checkbox"/> R3 <input type="checkbox"/> R4 | |
| Root or Probable Cause (If CAR source is not as Investigation) | | | |
| CAR #06-0012 was issued to after d two lots of Part #100-580-4 and one lot failed incoming inspection because the overall length on 17 parts fell below the lower specification limit of .314". The initial implementation plan to perform 100% inspection on all subsequent parts for this dimension was not successful. The capability o manu cess to provide parts with a proper length has not been determined by | | | |
| CAR Owner | Responsible Department | Quality Assurance | |

| CAR Implementation Plan (Owner) | | | |
|--|--|--|--|
| Description of Corrective/ Preventive Action to be implemented: | will begin capturing the data that is currently obtained during their in-process inspection procedures for the length dimension on the 100-580-4 part. The capability of the process will be determined from the data and appropriate actions will be taken to improve the capability as necessary. The current inventory levels for the 100-580-4 part will be sufficient for 3 to 4 months of production. Once begins manufacturing the 100-580-4 parts again, they will be required to provide in-process inspection data and capability measures for the length dimension of the 100-580-4 part. | | |
| Implementation Due Date | 05/31/07 (Provide date to CAPA Coordinator within 14 days of CAR initiation) | <input type="checkbox"/> CAR Implementation Due Date Extended (Attach Form #411104 for each extension) | |
| Additional Team Members Requested? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Name Department Name Department | | |
| Proposed Criteria to Determine CAR Effectiveness | Th inspection data and process capability for the length dimension must be provided by manufactured fc The next three production lots must not fail for a non-conforming length dimension. | | |

| Initial Plan Approval (Owner, Owner's Supervisor, & CAPA Coordinator unless resources added) | | | |
|--|-------------|---------------|--|
| Owner | | Date 10/25/06 | |
| R&D | | | |
| Manufacturing | | | |
| Quality | | 10/25/06 | |
| Other | | | |
| RA | | | |
| CAPA Coordinator | Cindy Jones | 10/25/06 | |
| Provide Original to CAPA Coordinator After Approval | | | |

Reactive work assignments | 2/2



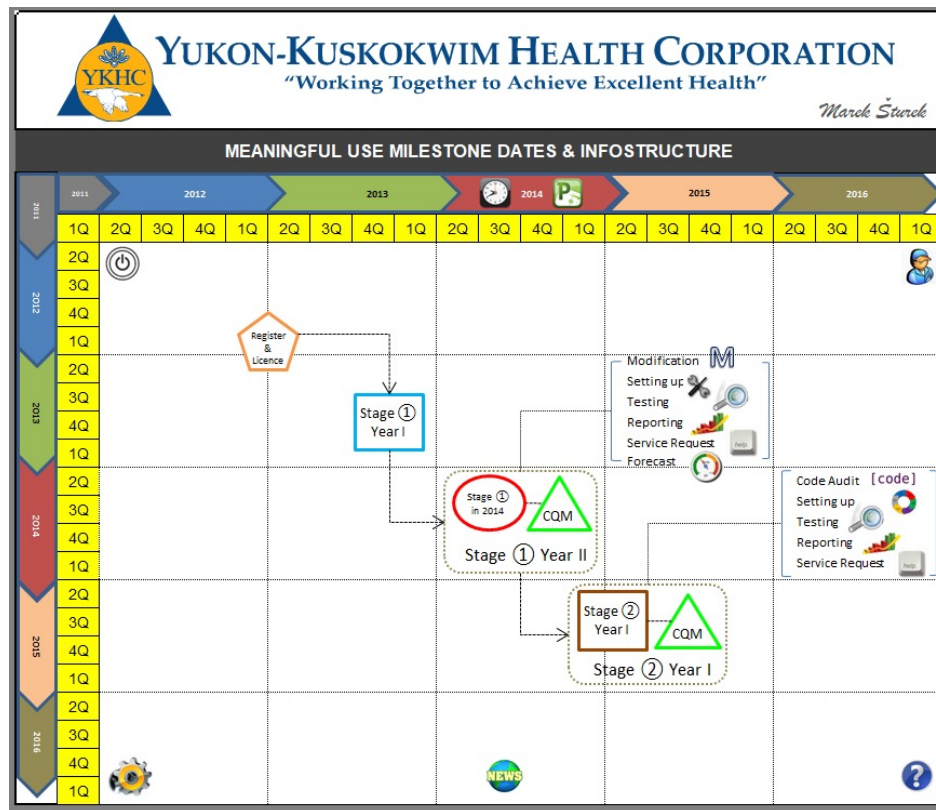
| Project Charter | | Date: 31-January-2011 | | Project Name/QTRAK Number: LSPR00020375 | |
|---|--|-----------------------|---|---|-------------------------|
| Problem Statement | | | Project Y | | Path Y's (If needed) |
| Diamond coating yields at diamond coater, causing shortages, affecting , are below 96% to meet customer demands | | | Production yield (PY)>97%) | | Rolled Throughput Yield |
| Project Goal | | | Scope | | |
| Increase diamond coating yields at I to greater than 97 % by August 2011 | | | Scope includes: Diamond coating process through receiving inspection at Medtronic | | |
| | | | Scope excludes: Transit, stem material, Medtronic packaging | | |
| | | | Do not harm: Dimension of the product, durability of diamond coating | | |
| Resources | | | Business Impact and Benefits | | |
| Project Team <ul style="list-style-type: none">Julie MouzakisRichard CastellanosGlenn NolleyMarek Sturek | | | Schedule: <ul style="list-style-type: none">Project start date: January, 2011Estimated project completion date: August, 2011Estimated date when benefits will begin: June, 2011 | | |
| Support Team: <ul style="list-style-type: none">Kristin Hughes (MBB)Ross Smith (PO, SSBB) | | | Benefits: | | |
| Stakeholders: <ul style="list-style-type: none">Tony Knight (CH)Dan Robinson (VSM)Dan Cleary (F)Humacao PR (C.S)Di-Coat Corp. (S) | | | Hard savings: Estimated MPSS's scrap cost of \$41K, Di-Coat's cost \$31K. NCR scrap cost of \$5K. | | |
| | | | Soft savings: Reduce non-conformances, reduce rework | | |
| | | | Other benefits: Strengthen partnership, Documented process controls | | |

LEAN SIGMA SOLUTIONS™ -

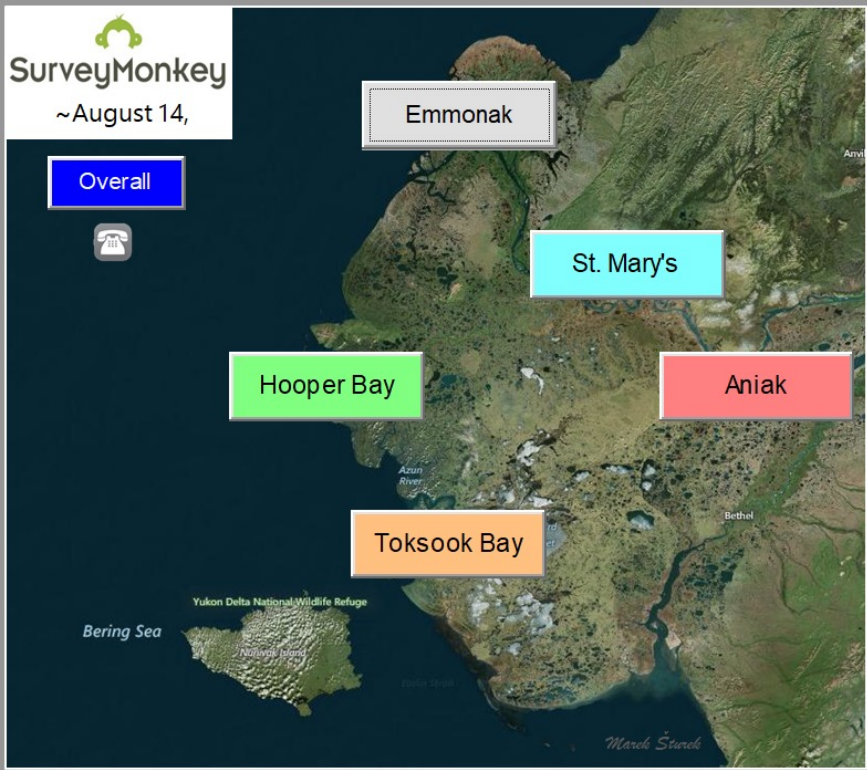
| Lean Six Sigma Di-Coat Corp. Production Project | | | | |
|---|---|--|------------------------------------|---|
| I. NCR Reduction | 1 | January-May 2011(Prior Improve Phase) | | June - August 2011(Current State) |
| | | Quantity (No.) | Cost (\$) | Quantity (No.) Cost (\$) |
| | | 4 | 3485 | 0 0 |
| II. Scrap Reduction | 2 | January-May 2011(Prior Improve Phase) | | June - August 2011(Current State) |
| | | Quantity (pcs) | Average Scrap (%) | Quantity (pcs) Average Scrap (%) |
| | | 1868 | 4.684 | 1305 2.087% |
| III. Component Quantity | 3 | January-May 2011(Prior Improve Phase) | | June - August 2011(Current State) |
| | | Quantity (pcs) | Average monthly receipts (pcs) | Quantity (pcs) Average monthly receipts (pcs) |
| | | 49327 | 9865 | 61284 20428 |
| IV. Savings | 4 | Di-Coat Corp. Savings | | Medtronic Inc. Saving |
| | | 400 pcs X \$6 > \$2400 per month | | 400 pcs X \$10 > \$4000 per month |
| V. Other | - | - | | - |
| > MPSS Inspection time | 5 | Receiving inspection for curve burrs the same | | Receiving inspection for curve burrs improved (Ultrasonic cleaning process removed) |
| > Di-Coat Corp. Rework process | 6 | AVG Feb-May 2011(Overplated, Sparse) 9.08% | | AVG June-August 2011(Overplated, Sparse) 2.47% |
| > Inspection method variation | 7 | No visual methods of inspection established between MPSS & Di-Coat | | Visual methods of inspection established & aligned |
| > Di-Coat Corp. Operational & process metrics | 8 | Operational & process metrics the same | | Weekly meetings / Data collection / Data analysis established |
| What's next? | | Complete drawing revisions | Drive excellence to improve Op. 40 | Continue focus on XOMED curve burrs Complete transfer to Plant No. 3 |

Proactive work assignments | 1/2

| | | | | | | | | | | | | | | |
|---|--------------------------------|--|-------------------------------|-----------|-------------------------------------|--------------------------------|-----------|--|--|-----------|---|------------------------------|-----------|-------------------------------------|
| | RISK ANALYSIS WORKSHEET | Risk Analysis Tracking No: RAW07-0013 Rev: NEW | | | | | | | | | | | | |
| Initiator: JAMES ELLSWORTH <i>2-02-07</i> | | Date Initiated: 2/8/07 | | | | | | | | | | | | |
| Primary Event Description: (Include how the event was discovered and the facts surrounding the event.) Operator did not follow work instructions 4093600-10. 1. O-Ring was not coated with Midas Flex Lubricant prior to installation. 2. Also, step 4 of work instruction, inserting collet housing into compressor, nut was performed in the middle of step 3 before inserting collet carrier into collet housing. | | | | | | | | | | | | | | |
| Primary Event Source: (select one) <input checked="" type="checkbox"/> Internal Source <input type="checkbox"/> External Source | | | | | | | | | | | | | | |
| State Failure Effects: <input type="checkbox"/> See Attached 1. O-Ring could become damaged during installation. 2. No failure effect is associated to this particular sequence. | | | | | | | | | | | | | | |
| State Potential Clinical Effects: <input type="checkbox"/> See Attached There is no clinical effect of either situation 1 or 2. The risk is completely transparent to the doctor and patient. | | | | | | | | | | | | | | |
| State Potential Event Cause(s): <input type="checkbox"/> See Attached Operator error - not following work instructions. | | | | | | | | | | | | | | |
| SEVERITY <input type="checkbox"/> 4-Critical <input type="checkbox"/> 3-Major <input type="checkbox"/> 2-Minor <input checked="" type="checkbox"/> 1-Negligible | | | | | | | | | | | | | | |
| Rationale: 1. The purpose of the O-Ring on the collet carrier is to minimize vibration. Even if the O-Ring is cut, it will still serve its purpose. There is no risk to the doctor or patient. 2. Inserting the collet housing into the compressor nut prior to inserting collet carrier into collet housing has NO effect on the collet performance. Neither step is dependant on the other being performed in sequence. | | | | | | | | | | | | | | |
| FREQUENCY <input type="checkbox"/> 4-Frequent <input checked="" type="checkbox"/> 3-Occasional <input type="checkbox"/> 2-Remote <input type="checkbox"/> 1-Improbable | | | | | | | | | | | | | | |
| Rationale: Work instructions are provided for operator at every work station, but human error is occasional. | | | | | | | | | | | | | | |
| DETECTABILITY <input checked="" type="checkbox"/> 3-Not Detectable <input type="checkbox"/> 2-May be Detectable <input type="checkbox"/> 1-Readily Detectable | | | | | | | | | | | | | | |
| Rationale: 1. If the O-Ring is cut, it may not be detectable to the operator. 2. Performing assembly steps out of order would not be detectable unless found during an audit. | | | | | | | | | | | | | | |
| Calculate RPN Severity X Frequency X Detectability = RPN 1 X 3 X 3 = 9 | | | | | | | | | | | | | | |
| <table border="1"> <tr> <td><input type="checkbox"/> ≥ 24</td> <td>R1</td> <td>Intolerable Risk; must be mitigated</td> </tr> <tr> <td><input type="checkbox"/> 12-23</td> <td>R2</td> <td>Unacceptable risk; must be mitigated per Table 4</td> </tr> <tr> <td><input checked="" type="checkbox"/> 5-11</td> <td>R3</td> <td>Marginally acceptable; may require mitigation</td> </tr> <tr> <td><input type="checkbox"/> 1-4</td> <td>R4</td> <td>Acceptable; mitigation not required</td> </tr> </table> | | | <input type="checkbox"/> ≥ 24 | R1 | Intolerable Risk; must be mitigated | <input type="checkbox"/> 12-23 | R2 | Unacceptable risk; must be mitigated per Table 4 | <input checked="" type="checkbox"/> 5-11 | R3 | Marginally acceptable; may require mitigation | <input type="checkbox"/> 1-4 | R4 | Acceptable; mitigation not required |
| <input type="checkbox"/> ≥ 24 | R1 | Intolerable Risk; must be mitigated | | | | | | | | | | | | |
| <input type="checkbox"/> 12-23 | R2 | Unacceptable risk; must be mitigated per Table 4 | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> 5-11 | R3 | Marginally acceptable; may require mitigation | | | | | | | | | | | | |
| <input type="checkbox"/> 1-4 | R4 | Acceptable; mitigation not required | | | | | | | | | | | | |
| Approved By: (External Sources require Regulatory and Product Engineering Signatures, Internal Sources require Quality Engineering, Manufacturing Engineering, all product labeling and potential field impact requires Regulatory signature) | | | | | | | | | | | | | | |
| Department | Signature | Date | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Quality Engineering | <i>[Signature]</i> | 2-22-07 | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Manufacturing Engineering | <i>[Signature]</i> | 2-22-07 | | | | | | | | | | | | |
| <input type="checkbox"/> Regulatory | | | | | | | | | | | | | | |
| <input type="checkbox"/> Product Engineer (R&D) | | | | | | | | | | | | | | |



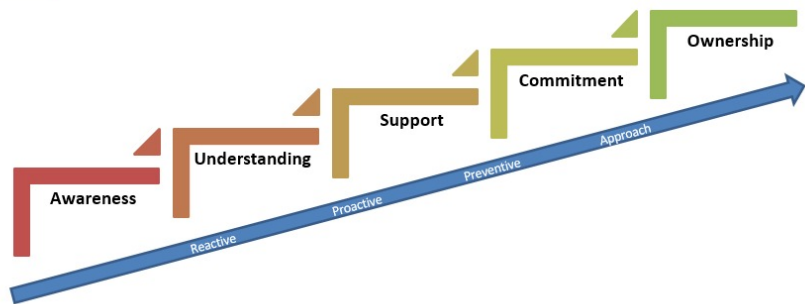
Proactive work assignments | 2/2



Preventive work assignments | 1/2



PI – Road to Success



Information sharing

Employee training

G4 Prioritization

Improvement Work Groups

PI Maturity & Integration

Sites Evaluation

System alignment with objectives

Leadership Team

Self Regulated Teams
"When mature"

Highly Reliable Organization

YVFWC Lean Training Blocks



Preventive work assignments | 2/2



| Task | Job | Standard Work | Department | Date |
|------|---------------|----------------|------------|------------|
| R1 | Acute Patient | YMDC Reception | Quality | 12/04/2017 |

Task Elements Owner: Front Office Supervisor

| | Description | If Critical | Key Points | Visual Cue(s) |
|----|-------------------|-------------------------------------|--|---------------|
| 1. | Greet the patient | <input checked="" type="checkbox"/> | Ask for D.O.B, First and Last Name, Introduce yourself. Let patient know who they are seeing and what time is appointment. | |
| 2. | Demographics | <input checked="" type="checkbox"/> | <p>Click on Appointment Desk Registration</p> <p>Demographics</p> <p>Patient Demographics</p> <p>General Information</p> | |

| HFMEA Subprocess Step Title and Number | | | | | | | | | | | | |
|---|----------|------------------------|-----------|------------------------|----------------------------|---------------|---|---------|--|--|------------------------|------------------------|
| HFMEA Step 4 - Hazard Analysis | | Decision Tree Analysis | | | | | HFMEA Step 5 - Identifying Actions and Outcomes | | | | | |
| Failure Mode: First Evaluate failure mode before determining potential causes | | Scoring | | Decision Tree Analysis | | | Action Type (Control - Accept, Eliminate) | | Actions or Rationale for Stopping | | Outcome Measure | |
| Potential Causes | Severity | Probability | Haz Score | Single Point Weakness? | Existing Controls Measure? | Detectability | Proceed? | | | | Person Responsible | Management Concurrence |
| | Major | Frequent | 12 | N | N | N | Y | | | | | |
| 1 Gender, Age in same room | Moderate | Frequent | 8 | Y | N | N | Y | N/A | State and Joint Commission regulations | | | |
| 2 High volume of patient | Moderate | Frequent | 8 | N | N | N | Y | Control | Review staffing plan for North Wing and ERI in order to establish more effective patient service | Effective patient service measured by Patient Satisfaction, Decreased length of stay | Cerrine, Reschke, Jeff | Barbara, Flag |
| 3 Staffing | Moderate | Frequent | 8 | N | N | N | Y | Control | > Create guidelines for admission > Review staffing plan on North Wing > Training status | | | |
| 4 Lack of guards | Minor | Occasional | 3 | N | N | N | N | Accept | | | | |
| 5 Intoxication (High acuity) | Major | Frequent | 12 | N | N | N | Y | Accept | | | | |
| 6 Insufficient # of room | Major | Frequent | 12 | N | N | N | Y | Control | | | | |
| 7 Mechanical issue | Moderate | Uncommon | 4 | N | N | N | Y | Control | | | | |
| 8 Standardization | Moderate | Occasional | 6 | N | N | N | Y | Control | | | | |
| 9 Waiting Judge, API Response, BH clinical | Moderate | Frequent | 8 | N | N | N | Y | Accept | | | | |

Bed availability (Inpatient 3 beds, ER 2 beds)



What can I do

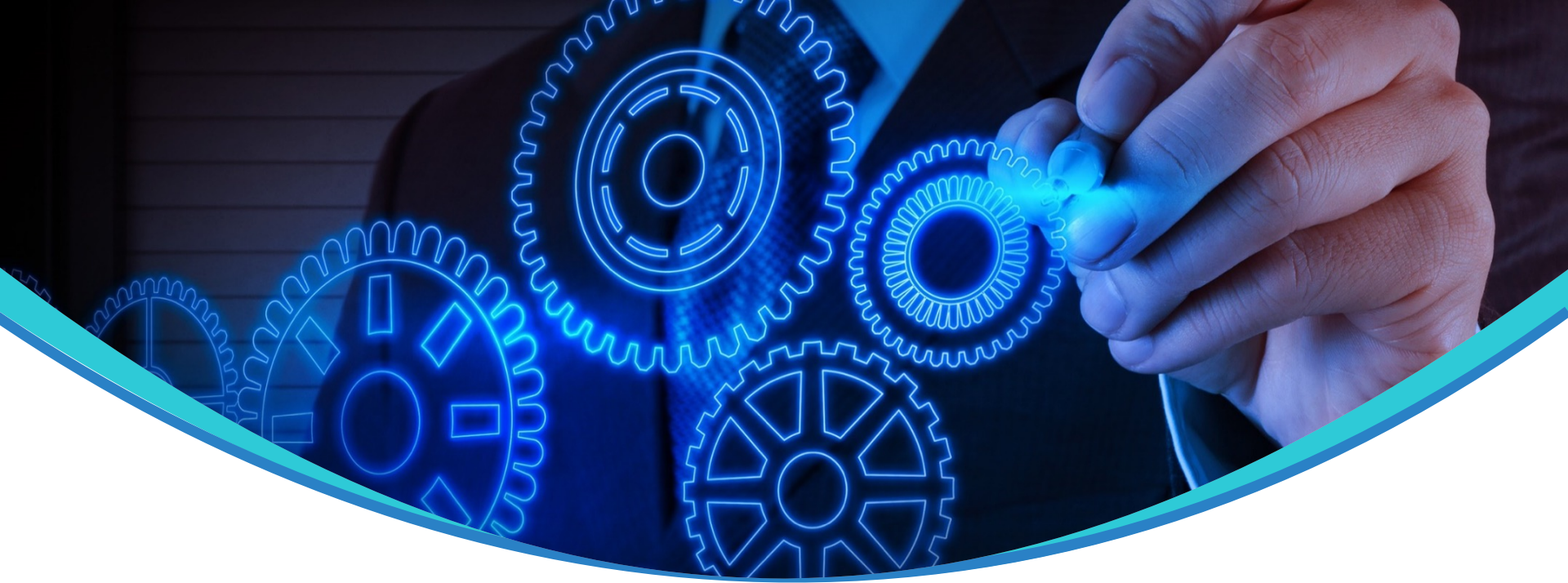
how to overcome obstacles

8 steps according to **JOHN KOTTER**

- Urgency of change
- Coalition supporting change
- Clear vision
- Communication of vision
- Stronger employee engagement
- Short wins
- Support of next change
- Hardwiring change



Today Not Tomorrow



Thank you & Questions

