Stable Operations, an efficiency innovation case study

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KCI Manufacturing Ireland

Engineers Ireland Seminar
“Talking Lean to the Next Level”
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Products & Manufacturing Process
Disposables: Sterile Canisters & Dressings

InfoV.A.C.® 500 ml Canister

V.A.C.® Simplace™ Dressing System

ActiV.A.C.® 300 ml Canister

V.A.C.® GranuFoam™ Dressing System
Negative Pressure Wound Therapy (NPWT)

- Removes exudates and infectious material from the wound
- Creates an environment that promotes healing and granulation tissue
To better understand the manufacturing environment and context in which “Stable Operations” was implemented, the following short 2 min video ...

KCI Manufacturing in Athlone
“High volume Automated assembly Canister & Dressing Disposables”
Background & Program Drivers
Business Drivers

► Background
KCI is committed to successful clinical outcomes and patient care. Process improvement must align with what Customer Value, translated into business objectives that flow from the enterprise into meaningful Operational objectives.

► Context
A changing environment in our sector
- Medical Device Tax, Medicare reimbursement under review ... sales price pressures
- Half of all Disposables outsourced at contract manufactures in low cost geographies ... they are >10% cost favorable ...

High volume Disposals BU in Athlone targets 3x key objectives in 2012:
- Leverage Overhead, +20% volume in a “In House Make versus Buy”
- Product and process changes to target 10% Direct Materials cost out, NO impact to availability & service levels !!!
- NO increment to the installed base, Fixed OR Variable overhead
Stability thinking, some principles
Measuring Stability …

In practice, histograms of Hourly Output when plotted tend to be “Negative Skewed” distributions where conventional descriptive statistics are not adequate to describe them;

For “Non Parametric” distributions, more often alternative parameters apply:

1\textsuperscript{st} Quartile : 25\textsuperscript{th} percentile value of hourly output, < Q1 are hours of low output and “Special Causal” drivers
2\textsuperscript{nd} Quartile : 50\textsuperscript{th} percentile value of hourly output, a mid point in the distribution
3\textsuperscript{rd} Quartile : 75\textsuperscript{th} percentile value of hourly output, > Q3 are hours of high output and “Special Causal” drivers

Between 1\textsuperscript{st} Quartile and 3\textsuperscript{rd} Quartile : are 50\% of all hours and are “Common Causal” frequent events

... using the parameters, we can express output variability as a ratio;

\[
\text{Stability Factor (SF)} = \frac{Q_1}{Q_3}
\]
Stability Thinking …

To achieve “Stable Operations” the following are **must** have prerequisites:

- One common metric at all levels across the entire organisation
- A robust measurement system (GR&R)
- Data drives all decision making
- Confidence in the data

Move the mean by attacking the variance!
Stable Operations demands a **paradigm shift**!

- The initial emphasis is on understanding & eliminating “variation” drivers around Q1 output performance.

Only when output stability has been demonstrated are we **Entitled** to shift the “mean”!
Prerequisites to “Getting it done”
Stability “Roadmap”

Change the Rules of the Game......

- **Unit of Measure Equal for All**
  - Smallest entity, the unit is granular ... Out’s in the hour
  - Hours off target, classed defective hours < Q3
  - Data collection, focal point at constraint

- **Stability Oversight & Daily Rigor**
  - By Hour : data integrity ... off-target defect hours direct cause drill down
  - By Shift : rolling 12 hour shift performance, causal data integrity
  - Daily : x-functional challenge defective hour data, direct & root cause(5 Why’s)
  - Weekly : data trending to identify common cause variation (80/20 rule)
  - Monthly & Quarterly : vital few focus improvement projects

- **Scheduling**
  - No internal optimization rules
  - Never early, Back Orders go first
  - Run sequence respects “EPEI wheel” optimized for output Stability

- **Digitization; one data source ... visibility of data to all !**
  - 1st start with manual data collection
  - 2nd leverage control systems to assist data collection

A PROVEN approach in Production and Support environments
Getting it done ...

<table>
<thead>
<tr>
<th>Operational Roadmap &amp; Approach</th>
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</thead>
<tbody>
<tr>
<td>Line of Sight Equal for All ... Based on Defects vs Target, hourly level</td>
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<tr>
<td>Review Structure ... <strong>Daily</strong>, All Decision Takers to Drive the hour</td>
</tr>
<tr>
<td>... <strong>Weekly</strong>, to Improve the Process</td>
</tr>
<tr>
<td>... <strong>Monthly</strong>, to Improve Business Processes</td>
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<tr>
<td>Process Leaders... Execution of Improvement</td>
</tr>
<tr>
<td>Data Analyze and Process focus</td>
</tr>
<tr>
<td>One Data Source ..... Common Database, On Line Available</td>
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... One Single Approach Across the Board!
Stability Program Oversight

Who?
- BU Leadership team
- Functional Leaders
- Business Leaders
- CI Leader
- BU Supervisors & Leads
- Maintenance Leads
- BU Engineers & Quality
- Supply Chain & Planners
- Warehouse Lead
- Operators
- Line Leads
- Shift Supervisors
- Technicians
- Warehouse Lead

What?
- Week review, Month & Qtr. Direction:
  - Stability attainment (SF, Q1, Q3)
  - Top Variance drivers & Mean shift priorities
  - Target setting (SF & Q1 = Q2)
  - Decisions and strategic consequence
- Daily Floor x-functional reviews:
  - Rolling 24 hours (SF, Q1), defect hours < Q3:
    - Direct & Root Cause?
    - Direct corrective action?
    - Root Cause “Why, Why, Why...”?
    - Support Needs
- Shift & Pass Down (defects < Q3):
  - D. Time drivers – where & what?
  - Direct Cause?
  - Direct Action?
  - Root Cause “Why, Why, Why...”?

Mgt. Control & Reporting System – everyone at their level has a role!
Stable Operation Outcomes
### Stability Outcomes

#### Automated Canister Line - Output Stability

**Note! Direct Materials Cost Out Program and changes implemented;**

Multiple product & process changes required impacting Output Stability July – Sept. 2012. The focus & rigour of the early 2012 Stability program launch aided the focus and a quickly recovery within 12 weeks without any “Stock Out” at our customers!

**Base Line Dec & Jan. 2012**

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>SF</th>
</tr>
</thead>
<tbody>
<tr>
<td>496</td>
<td>909</td>
<td>1,119</td>
<td>0.44</td>
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**Output Stability Jun. 2012**

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>SF</th>
</tr>
</thead>
<tbody>
<tr>
<td>778</td>
<td>1,017</td>
<td>1,161</td>
<td>0.67</td>
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**Output Stability Jan. 2014**

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>SF</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,000</td>
<td>1,212</td>
<td>1,345</td>
<td>0.74</td>
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From 904 to 1,212 Canisters/Hour ≈ 25% Up Lift !!!
Automated Dressings Line - Output Stability

Output per Hour

Stability Outcomes ...

From 769 to 1,276 Dressings/Hour ≈ 60% Up Lift !!!
Stability Outcomes in Summary

► Business Impacts;
Stable Operations is two years further on from implementation:

- Output uplift +50% in the available hour, requiring -30% less available hours to produce +15% more output!

- KCI Mfg. Ireland unit costs are 10% favourable over external contract manufacturers

<table>
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<tr>
<th>Volume %</th>
<th>Ireland Mfg.</th>
<th>Outsourced Mfg.</th>
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<tr>
<td>2010</td>
<td>43%</td>
<td>57%</td>
</tr>
<tr>
<td>2014</td>
<td>67%</td>
<td>33%</td>
</tr>
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- Dir. Material -10% cost reduction, demanded 5 significant product & process design changes. The newly established Output Stability focus aided a quick recovery within 12 week without “Stock Out” or risk to supply continuity.

- Planned Maintenance is 7% of down time in available hours.

► Employee Wellbeing;
Work Life Balance: year on year Over Time reduced from 700 in 2011 to 12 hours in 2013.
Stability Outcomes in Summary …

Stability Program as Enabler to cont. improvement:

- **EPE Interval**: from 4 to 2 weeks, Fin. Goods Inventory - 6% std. cost

- **LEAN methodology & Kaizen Events**:
  - C/O time reduction 6 to 2.5 hours: SMED, Work Content Combination Charts
  - Staffing Levels; Visual Staffing Plans, operator flexibility training/certification …
  - Leaning Batch Design History Record (DHR), 60% reduction in manual data field entry, GDP ….

- **RCM Strategy**:
  Risk Centre Maintenance (RCM); FMECA risk assessment, failure remediation strategies …

- **Defect & Variance elimination and process improvement projects**:
  - Ultrasonic welding characterization; DOE, vital setting tolerating, in process SPC …
  - Eliminate vision system false fails 4% scrap: Gauge R&R, pass/fail setting tolerating …

- .... many more …

Objectives were met while growing Functional Competencies ... a catalyst to CPD!
Thank You ... for your time today!