

Reduction of Non-Conforming Materials

Team: Vedant Murudkar, Prasun Abhishek Singh, Shivani Sadre, Anish Kumar, Pavan Shinde
Guided by: Prof Gary La Point, Champion: James Morse

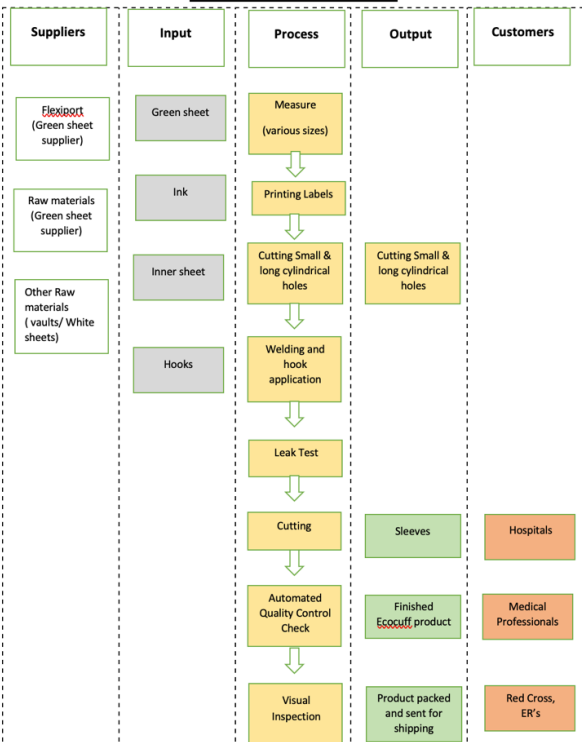
DEFINE

Problem Statement: FLEXIPOINT product line produced 15.6% of the defective products, which are causing a great financial impact to the company.

Business Case: Reducing the no. of defects from FLEXIPOINT product line will reduce the loss and holding cost of the company

Goal: Achieve a reduction in the number of defects from the Eco Cuff product line ranging from 15.6% to 7.00%.

SIPOC CHART



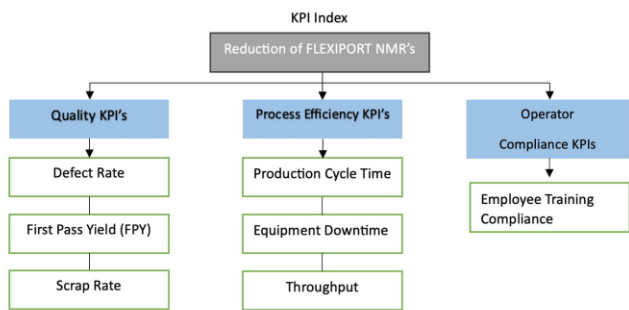
CTQC

Critical To Quality Characteristics Chart

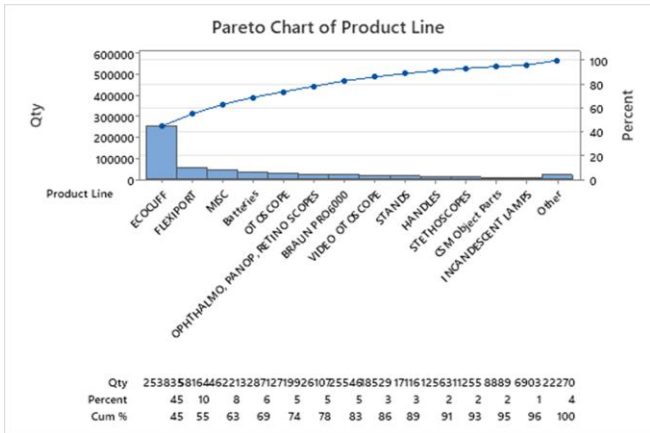
| Customers | Need | Driver | CTQC |
|----------------|---------------------------------|--|--|
| Baxter | Reliable & Defect free Cuff's | Quality production with less error | Production error |
| | Consistency in production | Skilled Workforce | Operator error |
| ER's, Redcross | Quality products | Reliability | Leak proof (Defect) |
| | Compliance and Safety standards | Quality management Systems, Regulatory Adherence | Adherence to Standards, Compliance measure & Tolerance dimensions |
| | Sterile Packaging | Health & safety Compliance | Must provide adequate protection during storage, proper packaging & Handling |

MEASURE

KPI



PARETO CHART



Since there were a lot of NMRs from different product lines, we decided to focus on the product line with the most NMRs. We created a pareto chart with quantities of NMRs from different product lines. From the pareto chart, it was clear that ECOUFF line produced 45% of the NMRs. So, we decided to focus on ECOUFF Product Line only to keep the scope of the project narrow due to time constraints.

DPMO CALCULATION

Number of Defects: 94617

Number of Unites Produced: 1,820,000

No of Opportunities per Unit: 4

DPMO = $(94,617 / 1,820,000) * 4 * 1,000,000$

DPMO = 207,949.45

DPU = DPMO / 1,000,000

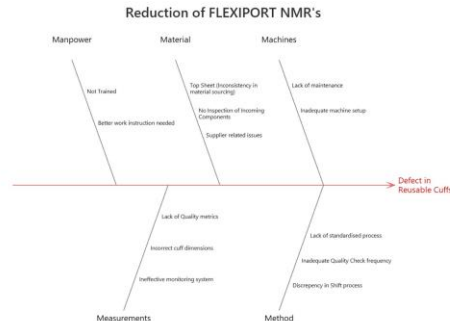
DPU = 0.20794945

Sigma Level = $1 / \text{Sqrt}(\text{DPU})$

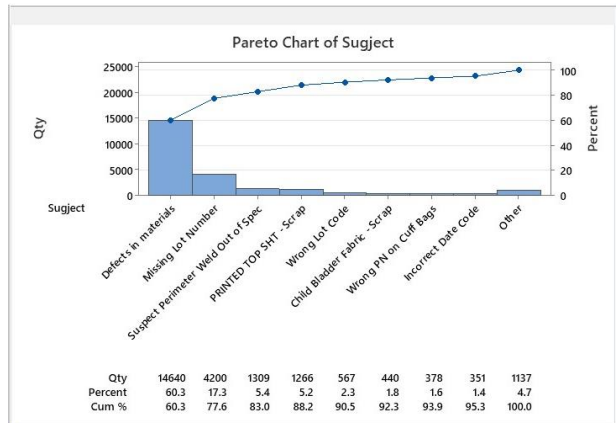
Sigma Level = 2.19

ANALYZE

CAUSE & EFFECT



PARETO CHART



From the pareto chart, it is visible that defect in raw materials was the major reason for the huge number of NMRs (around 60%). Following were some human errors in packaging and some welding defects.

IMPROVE

PILOT TEST:

| Date | Time | Leak Test (Pass/Fail) | Pull Test (Pass/Fail) | Dimension Test (Pass/Fail) | Visual Inspection Failure | Printing (Pass/Fail) |
|----------|-------|-----------------------|-----------------------|----------------------------|---------------------------|----------------------|
| 01/12/23 | 8:00 | P | P | P | N | P |
| 01/12/23 | 9:00 | P | P | P | N | P |
| 01/12/23 | 10:00 | P | P | P | N | P |
| 01/12/23 | 11:00 | P | P | P | N | P |
| 01/12/23 | 12:00 | P | P | P | N | P |
| 01/12/23 | 13:00 | P | P | P | N | P |
| 01/12/23 | 14:00 | P | P | P | N | P |
| 01/12/23 | 15:00 | P | P | P | N | P |
| 01/12/23 | 16:00 | P | P | P | N | P |

FMEA:

| Step/Process/Component | Potential Failure Modes | Potential Effects of Failure | Severity (S) | Occurrence (O) | Detection (D) | Risk Priority Number (RPN) |
|----------------------------|-------------------------|--------------------------------|--------------|----------------|---------------|----------------------------|
| Place the green sheet | Misplacement | Incorrect cuff assembly | 10 | 4 | 5 | 200 |
| Weld the port hole | Welding defects | Compromised cuff integrity | 10 | 2 | 8 | 160 |
| Print the dates and labels | Printing errors | Incorrect information on cuffs | 9 | 6 | 5 | 270 |

| | | | | | | |
|---|-------------------------|-----------------------------------|----|---|---|-----|
| Raw materials | Defective raw materials | Defective cuffs produced | 10 | 5 | 3 | 150 |
| Make the small circular and long rounded rectangular hole | Improper hole cutting | Inconsistency in cuff design | 7 | 2 | 5 | 70 |
| Stick the hook on the cuff | Adhesive failure | Detached hooks | 5 | 2 | 3 | 30 |
| Sand the cuff for smoothness | Inconsistent sanding | Rough or uneven surface | 5 | 1 | 4 | 20 |
| Perform a leak test | Test equipment failure | Undetected leaks | 9 | 3 | 5 | 135 |
| Print the date on the cuff | Printing errors | Incorrect date information | 8 | 6 | 5 | 210 |
| Manual Visual Inspection | Human error | Missed defects | 5 | 3 | 5 | 75 |
| Perform Pull Test on a sample | Poor Welding | Poor Cuff Strength | 10 | 3 | 5 | 150 |
| Perform Dimension Test on a sample | Human Error | Inaccurate dimensions measurement | 9 | 6 | 5 | 270 |

CONTROL

Control Plan:

| Date | Time | Leak Test (Y/N) | Pull Test (Y/N) | Machine setup (Y/N) | Dimensions entered (Y/N) | Part Number entered (Y/N) | Lot number entered (Y/N) | Top Sheet roll (Y/N) | Ink level (Y/N) | Sander check (Y/N) |
|----------|--------|-----------------|-----------------|---------------------|--------------------------|---------------------------|--------------------------|----------------------|-----------------|--------------------|
| 12/30/23 | 8:00am | | | | | | | | | |
| | 8:30am | | | | | | | | | |
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Recommendations

- Implement refresher training for the operator workforce, emphasizing adherence to manufacturing SOP.
- Create and adhere to a daily checklist template for documenting and reporting production data, quality metrics, incidents, or deviations, and reporting non-conformities.
- The current quality check frequency i.e. 1 sample every 4/8hrs is not efficient. Quality checks should be performed at the start of every new shift/production. If a defect occurs, take a sample again after half an hour. Else, once more after 4hrs from last check. If any defect occurred, take another sample after half an hour or else take one sample every 4hrs.

- Enhance process supervision, emphasizing accurate entry of dimensions, part numbers, & lot numbers. Improve inspection of FLEXIPOINT Top Green sheets, establish protocols for routine machine check-ups & maintenance.