Welcome ASQ Section 626 Members & Guests!

ASQ Central California Section 626

Proudly Presents

A Root Cause Analysis Presentation:
"Get At The Core!"

Sunrise Medical
2842 N Business Park Ave, Fresno, CA 93727
Tuesday, November 5th, 2019 at 5:30 pm

Agenda:

- 5:30 – 6:15 Registration & Networking – Light Snacks & Refreshments Served
- 6:15 – 6:30 ASQ Section Business and Announcements
- 6:30 – 7:30 Presentation and Questions
- 7:30 – 7:45 De-brief and Door Prizes ☺

Presenter Biography

- Devin I. McElroy is the Senior Director of Quality Assurance and Regulatory Affairs, North America, at Sunrise Medical in Fresno, CA.
- He earned his doctoral candidacy at Capella University in Minneapolis in 2017 and is currently completing his dissertation.
- McElroy is an ASQ senior member and an ASQ-certified quality auditor.

Get At The Core

Devin I. McElroy, Ph.D. (cand.), MBA/TM, CQA

Senior Director of QA/RA, North America

Sunrise Medical

Root Cause Analysis (RCA): What it *is* and is *not*

- It IS a problem-solving methodology that can identify the cause of a product defect.
- It IS performed to identify the primary initiating event for the cause of a product defect.
- It IS NOT one tied to one methodology.
- It IS NOT the only activity performed for solving product defects, it is only the first step.

When RCA is not applicable

- When a root cause falls outside the manufacturer's realm of influence (e.g., acts of god, raw material defects, deficient supplier practices, etc.)
- However, RCA can still be employed to identify the area that has contributed to the defect and some activities can be performed to help mitigate the defect.

Top 5 RCA Methodologies

1. 5-Whys
2. Cause-and-Effect (Ishikawa) or Fishbone Diagrams
3. Structured Brainstorming Techniques
4. Fault Tree Analysis
5. Value Stream Mapping

Root Causes

- Design defects
- Manufacturing defects
- Quality defects

- What is the most common defect identified in practice?

Human Error!

How to fix Human Error

- First of all, you can't. Human error is a given; humans *will* err.
- Replacing or retraining the human will not provide a permanent fix. Why not? Because:

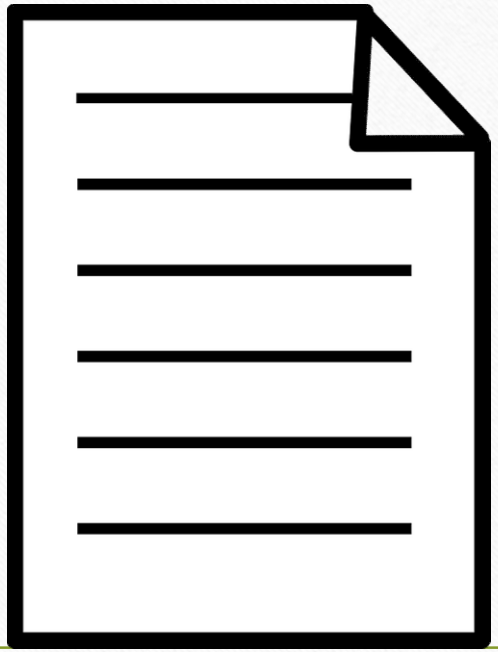
HUMANS WILL* ALWAYS *ERR

So, if we can't fix Human Error, what can we do about Human Error?

A good corrective action must be controllable by the manufacturer. You can't fix human error, but you can mitigate the impact and you can fix many of the causes of human error.

Causes of Human Error:

1. Confusing procedures



Causes of Human Error:

2. Internal (personal) distractions

Causes of Human Error:

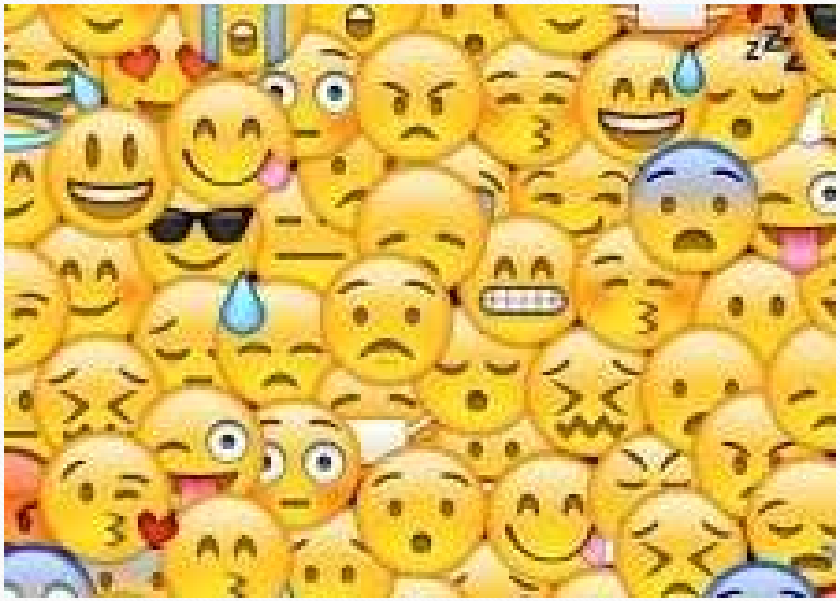
3. External distractions

Causes of Human Error:

4. Unaware the procedure existed

Causes of Human Error:

5. Procedural updates

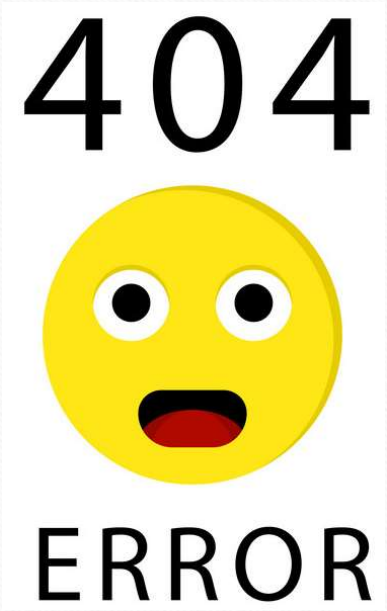


Causes of Human Error:

6. Intentional misuse or willful misconduct

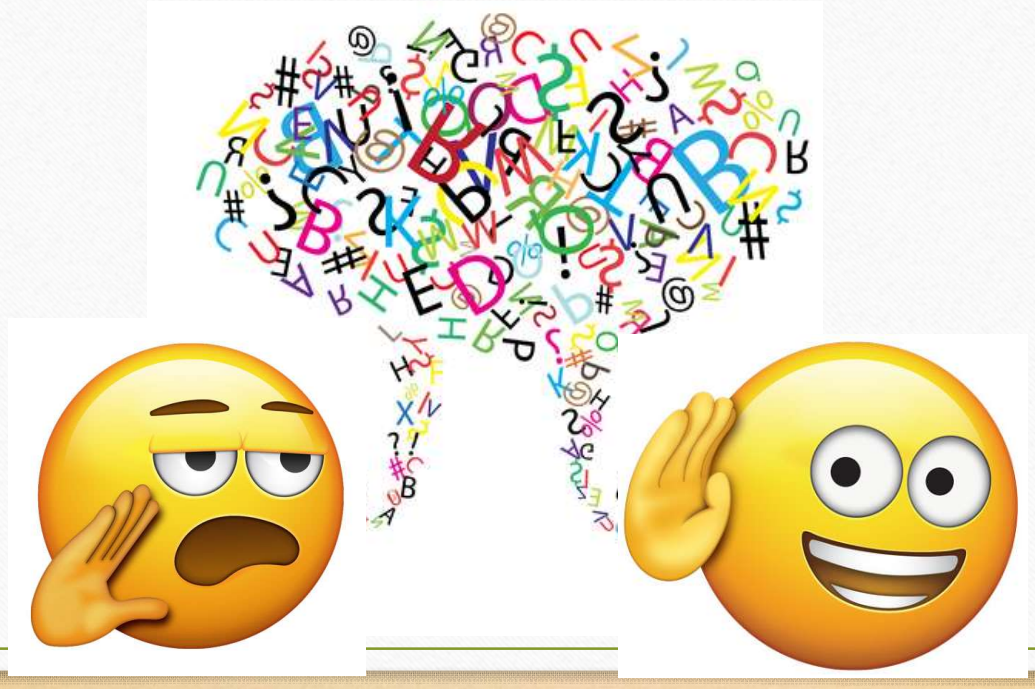
Causes of Human Error:

7. Inadequate electronic access



Causes of Human Error:

8. Missed a Step



Causes of Human Error:

9. Inadequate paper-based systems

Causes of Human Error:

10. Inadequate software systems

Causes of Human Error:

11. Employee Apathy

Causes of Human Error:

12. Employee unable to perform certain steps

Corrective Actions

- Favorite Corrective Action = Retraining
- Ask yourself: Does retraining work, if:
  - The problem is employee apathy
  - The problem is wrong equipment
  - The problem is a confusing procedure

Corrective Actions

- Look at the event that precipitated the human error. If the cause is:
  - **Lack of a consistent process**, then a procedure may be needed.
  - **Manual process**, then a fixture may resolve the issue
  - **Different language**, then procedure may need to be rewritten in specific language
  - **Willful misconduct**, then PIP or dismissal may be needed

Conclusion

Addressing the event that precipitated, caused, or contributed to the human error will result in the reduction of future recurrences of human error. Ultimately, this will have a positive outcome on lowering manufacturing defects.

Q&A

devin@dmcelroy.com

Supplemental Materials

Bibliography

1. Burk, James A., and Hendry, Janet A. “Planning and tracking risk reduction to completion.” *Professional Safety*, May 2015, 30.
2. Fehr, Gregory. “How to avoid future problems based on previous failure analysis.” *Leadership and Management in Engineering*, January 2012.
3. Haigney, Susan. “Human Error and Retraining.” *Journal of GXP Compliance,* Autumn 2009, 47-60.
4. Harvey, Tom. “Reducing the frequency and severity of human error: Optimizing Performance.” *Professional Safety*, November 2013, 39-42.
5. Myszewski, Jan M. Improvement story by 5 Whys. *The TQM Journal*, 25(4), 371-383.
6. Schnoll, Les. “Corrective and preventive action in medical device manufacturing.” *Quality Progress*, November 2001, 75-82
7. See, Judi E. “Visual inspection reliability for precision manufactured parts.” *Human Factors* 57 (8): 1427.
8. Spencer, Karen. “Getting to the root cause.” *Quality*, July 2015, 42-45.
9. U.S. Food and Drug Administration. *Quality System Regulation*. Code of Federal Regulations, Title 21, Part 820, April 2015.
10. University College London. “How believing can be seeing: Context dictates what we believe we see.” *ScienceDaily.* www.sciencedaily.com/releases/2008/02/080215103210.htm (accessed July 25, 2016).
11. Vidyasagar, A. The art of root cause analysis: Five whys analysis to ask the right questions at the right time. Quality Progress, February 2015, 48.

Get At The Core