



# Process Quality & Improvement:

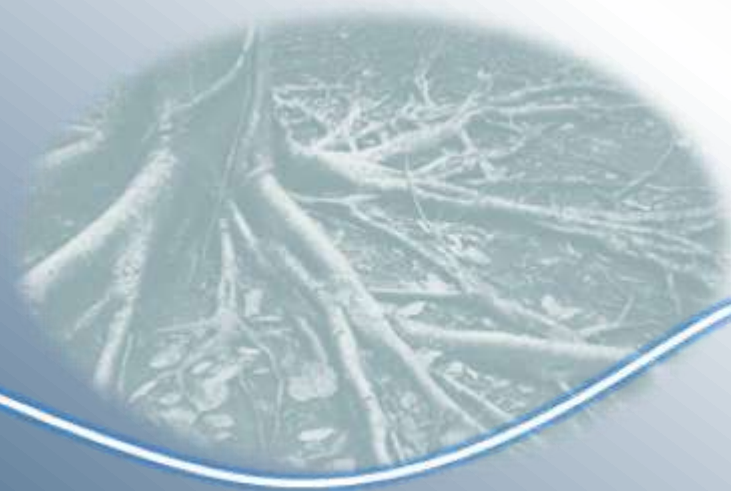
*Using Process Quality Data To  
Drive Root Cause Analysis And  
Continual Improvement*

Kerry Jones, MS

# \* Why is Quality Data Important?

## Compliance

- \* FDA 820.100
- \* ISO 9001 8.5.2
- \* EPA Standards
- \* GMP Standards



# \*Definitions by ASQ

- \*Root Cause: A factor that caused a nonconformance and should be permanently eliminated through process improvement
  - \*Process: A set of interrelated work activities characterized by a set of specific inputs and value added tasks that make up a procedure for a set of specific outputs
- \*Improvement: The positive effect of a process change effort



# \*Key Definitions for Today

- \* Data: A set of collected facts
- \* Quality: A subjective term for which each person has its own definition
  - \* The characteristics of a product or service that bear on its ability to satisfy stated or implied needs
  - \* A product or service free of deficiencies



# \* Investigation Basics

A3 Investigation

Background- *Owners, why are you investigating*

Data and Analysis - *What do you know and what do you think it means*

Root Cause Analysis - *RCA Tool*

Possible Solutions - *All possible ways to solve the problem and evaluations*

Implementation Plan and Monitoring - *How to put the solution into place and how will you know that it fixed the problem*

Parking Lot- *Ideas not to forget*

# \*Where to Start?

\*Hardest part about finding the root cause??

\*Figuring out what the problem is that you are trying to find the root cause of

Who? What? When?  
Where? How?



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# \* Get below the surface

- \* What Band-Aids have you already applied to this issue?
- \* What is not a symptom?
- \* “Why?”





# \* How do you define the problem?



\* Collect Data



*What is Data?*



# \*To Be or Not to Be Data

Reason for rework  
Process Steps  
Cost  
Audit Findings  
Customer complaint

Number of Successes  
Time  
Type of rework  
Amount of defect  
Employee complaints

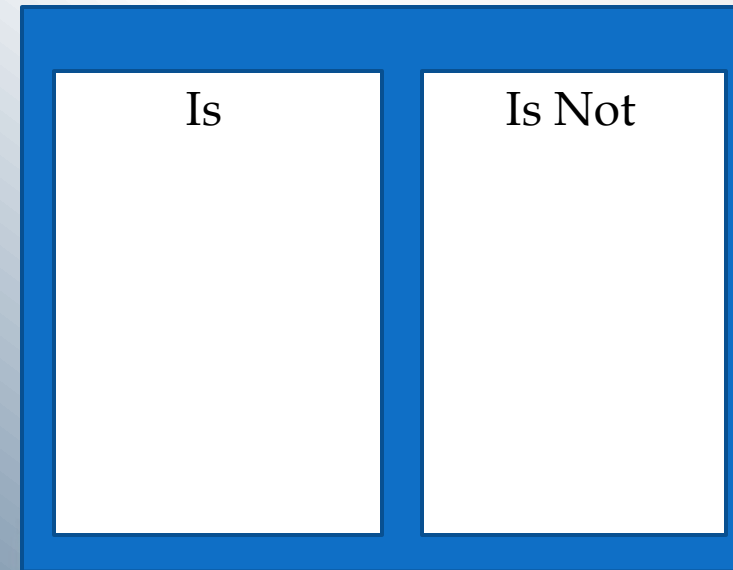
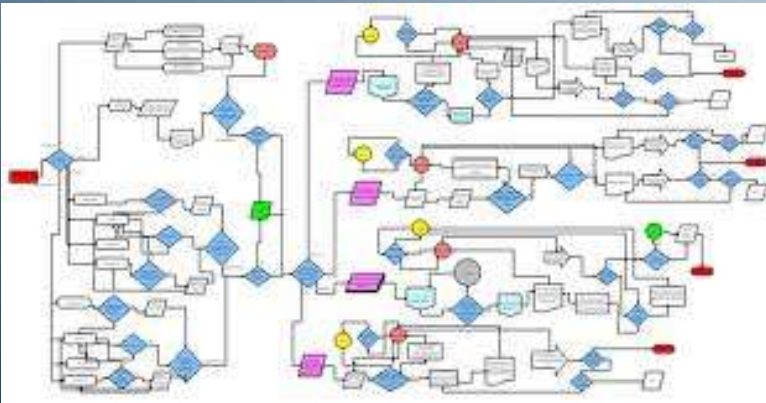
Number of failures  
Statistical Control Charts  
Number of errors  
Source of frustration  
Regulation  
Workload

*That is the answer*



# \*How Much Data do you Need?

- \*How complex is the Problem?
- \*How clear are the symptoms?



Is/Is Not  
Process Map

# \* How do you know it's a good problem statement?

- \* Only 1 problem at a time
- \* No cause
- \* No solution
- \* No one at fault
- \* "Should" is identified



# \* Now that you have the right question

\* Data doesn't have meaning  
until you interpret it

Why do I care?  
and

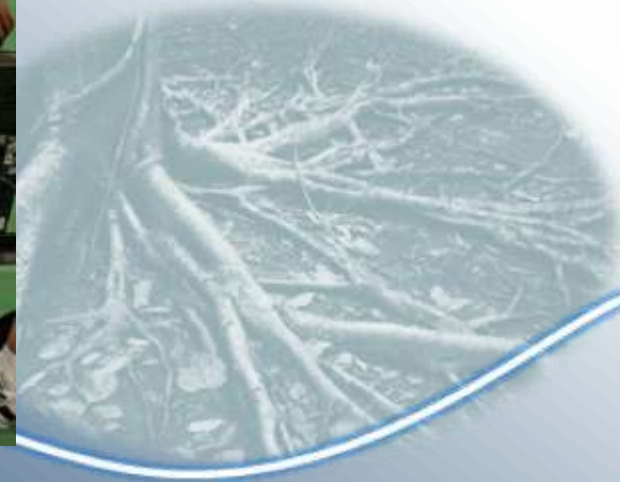
What do I care about?



Dig Deeper

# \* After Further Review...

Does the problem statement still make sense?



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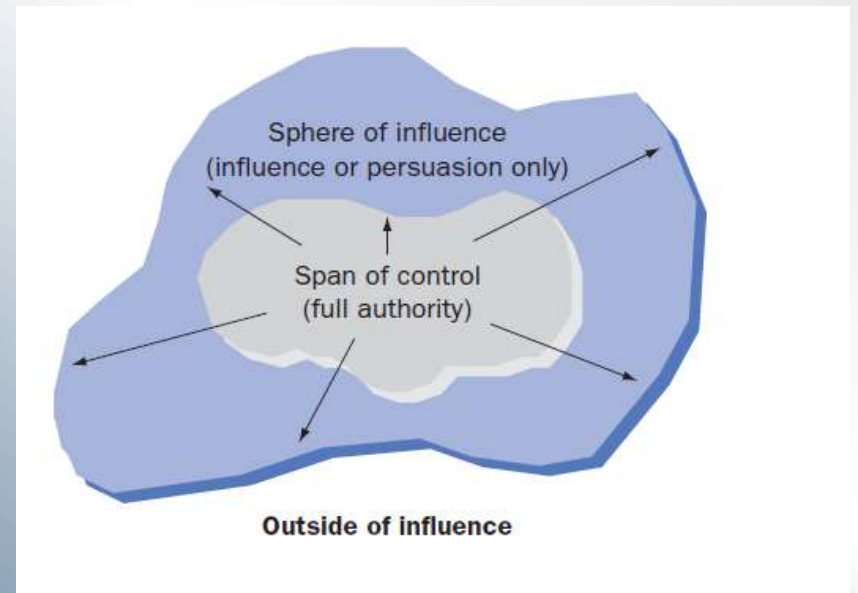
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# \*When to Stop Digging

\*Sphere of influence





# \* 5 Whys

Why?

Why?

Why?

Why?

Why?

Why?

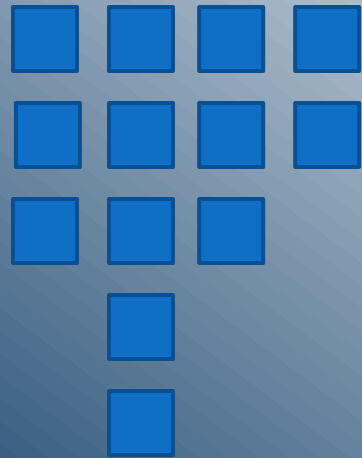
Why?

Why?

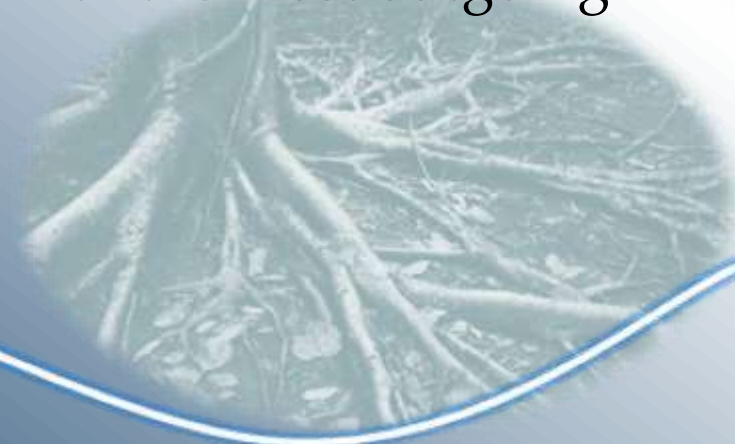
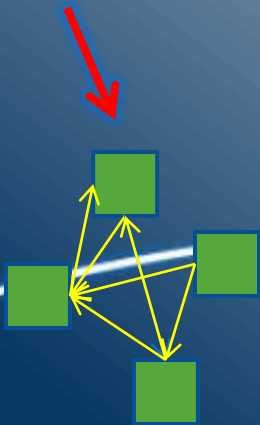
- \* Purpose: peel away layers of symptoms
- \* When to Use: simple and focused issues, no numerical analysis
- \* Data Needed: initial problem statement and the GEMBA
- \* Consider for Success: ok to backtrack, answer must address the problem
- \* Root Cause: when the answer to why remains the same



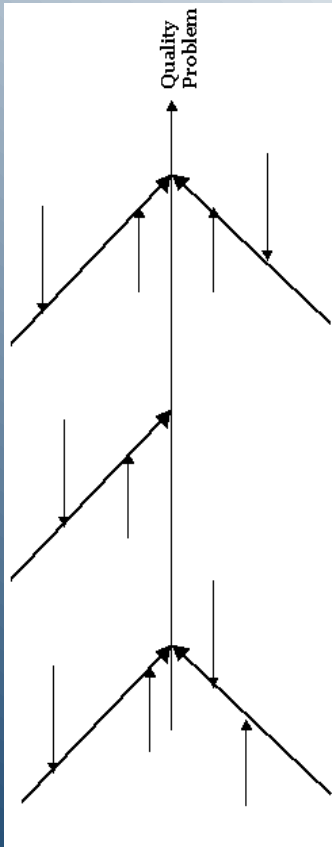
# \* Affinity/Interrelationship Diagram



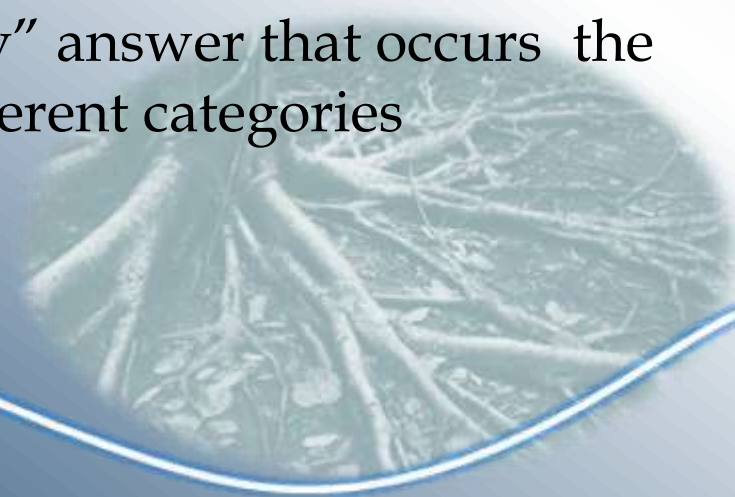
- \* Purpose: Sort through large amounts of information to identify links among related items
- \* When to Use: Multifaceted problems
- \* Data Needed: opinions, process steps, GEMBA
- \* Consider for Success: Brainstorm first, equal contributions, allow plenty of time
- \* Root Cause: the bucket with the most outgoing arrows



# \*Fishbone

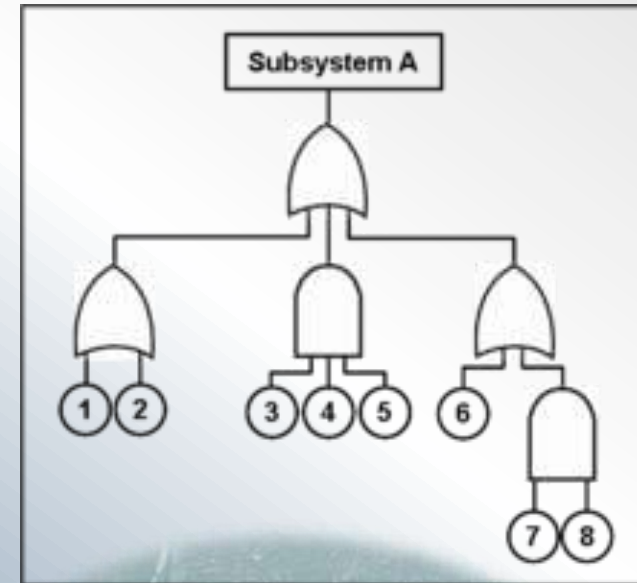


- \* Purpose: identify all possible causes in detail
- \* When to Use: when need to focus on causes inside and outside of companies control
- \* Data Needed: detailed problem statement, GEMBA
- \* Consider for Success: greater diversity needs greater time, for each cause ask “why does this happen?”
- \* Root Cause: is the “why” answer that occurs the most often through different categories



# \* Fault Tree

- \* Purpose: evaluate a chain of events
- \* When to Use: know the end but not what can keep you from getting there
- \* Data Needed: process steps and error identification, inputs, outputs, technical info
- \* Consider for Success: keep as simple as possible, clear and concise wording
- \* Root Cause: the input that you can do something about



AND or OR?

# \* Check Your Problem Statement



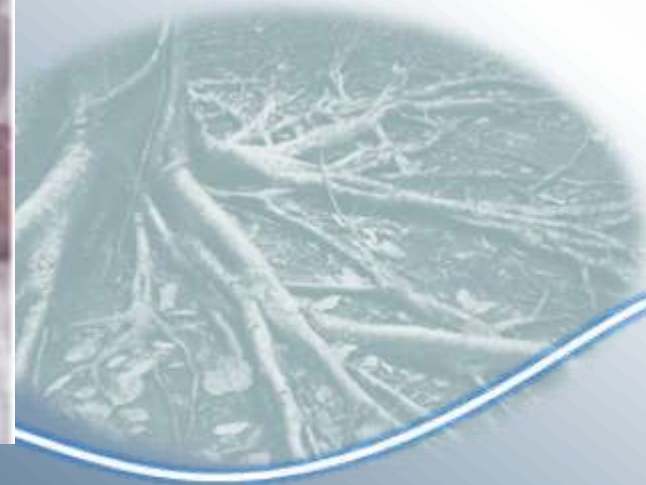
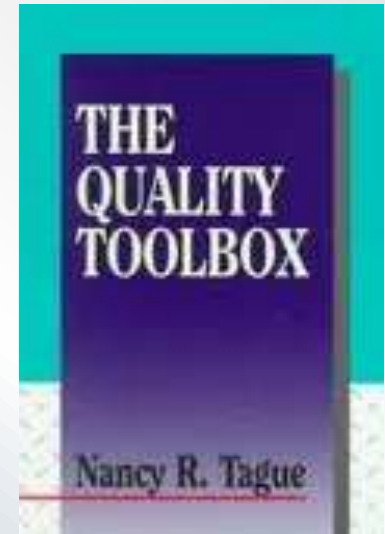
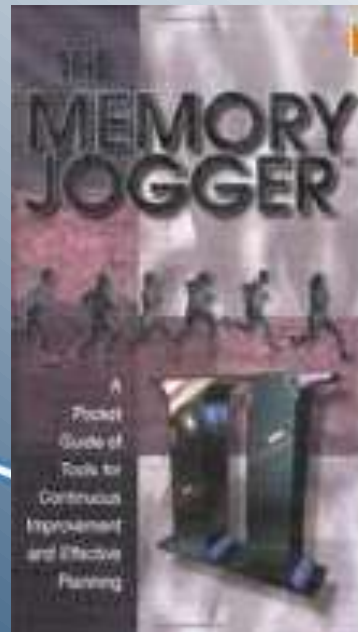
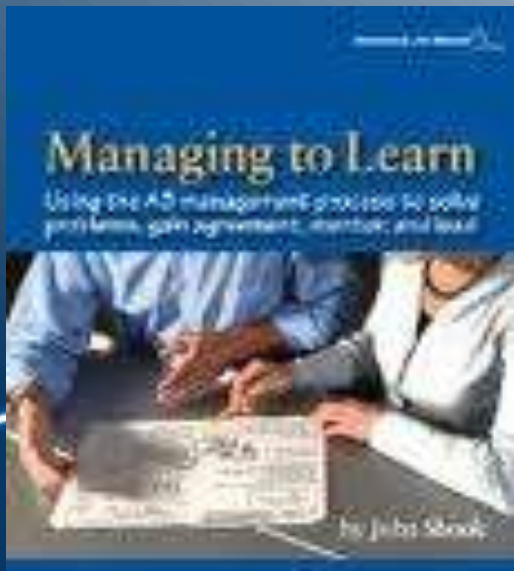
\* Does BECAUSE make sense?



# \*Resources

My go to resources

- \* ASQ
- \* Quality Toolbox
- \* Memory Jogger
- \* Managing to Learn



# Questions



# Lessons Learned

- Spend the time up front
- Who you ask is important
- Just because you can't quantify it doesn't mean you don't have data to work with
- The hardest part of RCA is leading people through it
- **MAKE SURE YOU ARE ASKING THE RIGHT QUESTION**

