# Root Cause Analysis

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# Agenda

- **Discuss RCA process**
- **Recognize need for another level for complex situations**
- **Understand alternative approaches**

**Lost experience – "what to do when stuck?"**

# Common Processes

- **PDCA (or PDSA)** — **Formal and informal situations**
  - **Plan, Do, Check (Study), Act**
- **DMAIC**
  - **Define, Measure, Analyze, Improve, Control, Sustain***
- **DMADV**
  - **Define, Measure, Analyze, Develop, Verify**
- **LAMDA**
  - **Look, Ask, Model, Discuss, Act**
- **8D**
  - **Plan, Team, Define, Interim containment, Find root cause and escape point, Verify permanent solution, Implement, Preventive measures, Congratulate team**





# The RCA Process

- **There are many "systems" to solve a problem. What matters most is what you emphasize.**
- **Solving a problem in R&D, manufacturing or in the field – really ends up being about the same thing.**

# Differences

- **The big additional item for manufacturing or field issues is to contain the bad stuff!**
  - **On order, in process, in storage, in field**
  - **Why is that seldom talked about? Seems critical to me.**
- **Short term and long term solution**





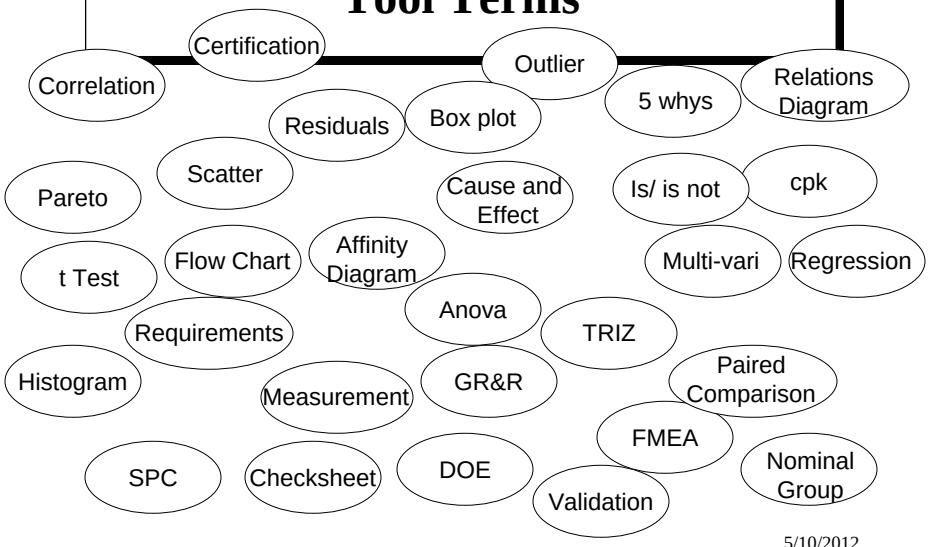
# 7 Simple Tools

- **Flow Chart**
- **Cause and Effect**
- **Pareto chart**
- **Histogram**
- **Scatter Plot**
- **Check sheet (map)**
  - **Data collection**
- **SPC (Statistical Process Control)**

Intent of tool is most important

**Life Science Alley**

# Tool Terms






**Life Science Alley**

# Root Cause Analysis Situation

- **How is it different than problem solving?**
- **Customers and vendors involved**
- **Lots of money on the table**
- **Complex problem, where the quick and dirty solutions did not work yet**
- **Likely been an issue for months or years**

# Dealing with Root Cause

- **If it is a suspect lot of material, then it should be dispositioned by the key stake holders**
  - **Do we use it until confirmed?**
  - **Do we pull it out of the process?**
  - **Do we return it to the supplier?**
  - **What if it passes the supplier spec, but does not perform for us?**
  - **Is our change something that could require customer approval?**
  - **Does our change even work?**
  - **Is there a way to rework the parts to pass?**
- **If it is known bad, then can we**
  - **Screen for it in the future**
  - **Change our design to be "robust" to it in the future**
  - **Change materials**
  - **Change our process**





# Weaknesses

- **We've been there before, we should be able to get back there again**
  - **Have you?**
- **Egos and control**
- **Rewarded for closing out items in short amount of time, prohibits time required to find a root cause**
- **Ignore interactions**
- **Test a point versus testing an area**

# Situation Examples

- Several black magic processes
  - Address internal first
- Several wide tolerances from vendors
  - Need to be stable over that range
- Development of complex, new technology
  - Redesign and major process changes
- Mold new part
- Not what it was, but still in their spec





# Common (bad) Approach As Executed

- Brainstorm list of possible causes
- Cross things off the list when evidence is provided that it was not the cause
  - Often an unsubstantiated claim/ opinion
- There are 2 or 3 remaining items…
- Quick tests (OFAT)
- Make data fit a cause
- Sign off the correction
- Resume production, hoping it does not return again

# As Executed

- **Find issue and resolve: quick and clean**
- **Stand off – memos "we didn't change anything. It's not our fault"**
- **Guess, guess, guess (informal, unstructured, but sounds like "scientific method")**
- **Is/ Is not (formal)**
- **Analysis (do the theoretical homework)**
- **Empirical results (knowledge)**
  - **"Just make it go away" – speed and stability**





# Decision Making Process

- **State problem (or opportunity)**
- **Identify alternatives**
- **Evaluate alternatives (funnel down number of choices)**
  - **Existing knowledge**
  - **Design and conduct experiments**
- **Make decision**
- **Implement**
  - **Does not need to be all or nothing, phased implementation is also an alternative (gathering more data)**

**Parendo, Minnesota Council for Quality, 2012**

# DOE Process

- Define goal / need
- Define response to measure progress to goal
- List all variables and down select to "key" variables using engineering judgment
- Select appropriate design matrix
- Select safe/consistent test levels for variables
- Address response priorities
- Perform test
- Analyze results
- Discuss next step

Parendo, MN ASQ Conference, 2001





# The Homework that Needs Done

- The work that should be done up front includes:
  - Knowing the requirements and their basis
  - Knowing the measurement system is representative
  - Understanding specifications for incoming materials
  - Understanding other design inputs – design variables
  - Understanding process nominals and extremes

## More on Homework

- **What we need is:**
- **“Help setting OQ limits and making sure the process limits are tied to a real specification with statistical evidence ("proof") of validity.”**





## When Need Advanced

- **Hit the wall**
- **It’s been “this” solution before, why not now?**
- **What if/ What else testing**

- **How often? Probably not more than 20% of the time…**
- **Depends on maturity of project**

# Advanced Techniques

- Cause and effect with Is/ Is not chart
- Simulations/ Digital Manufacturing (white paper – coming soon on my website)
- DOE (Product and Process)
- SPC (incoming and in process)
- Risk management





# Is/ Is Not Chart

- This collects information about the situation
  - What the problem is and what it is not, and if those positions are based on fact or opinion
- The biggest danger is that it looks at things in a "One Factor at a Time" manner. We can show it is not a main effect – but if it was, we would have noticed much quicker
- Once crossed off the list, it then is not considered for interactions and DOE related work
  - Doing a DOE on the 2-3 remaining this is not going to work, as they are often less likely items if no previous information existed

# What can make this effective

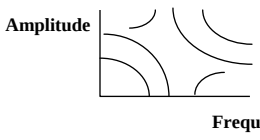
- **Simulations can enhance understanding**
- **Test strategies to confirm understanding**
  - **Verification testing over a period of time/ lots to ensure stability**
    - **Basing this on weak assumptions is dangerous – a potential schedule savings if accurate. A frustrating, head scratching adventure if not.**
  - **Development tests that address the "what ifs" involved**
    - **Understanding the "design window"**
    - **Understand the margins and the nominal**
    - **I have not found a better approach to do this than Design of Experiments**





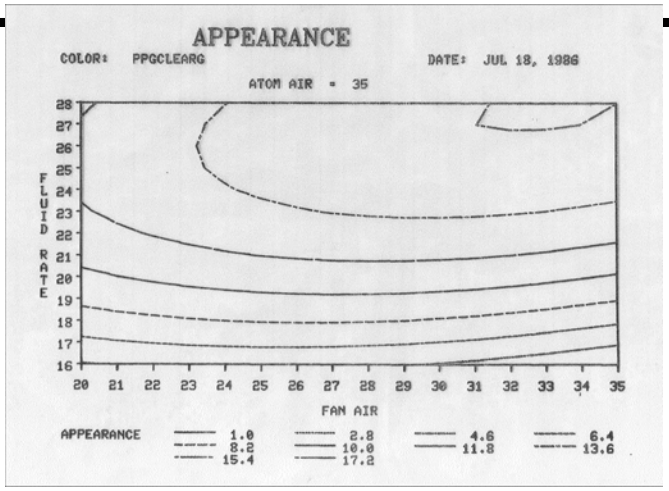
# Injection Molding Example

- **Goal: Predicting where to operate would be great! Need to rebuild trust with customer.**
- **Response: leakage and appearance**
- **Approach: Executed first DOE at vendor recommended ranges**
- **Result: Found "bad" and "ok" areas; could predict better area!**




* **Predicted operation area**

# GM Chart








# Conclusion

- **The process and tools are fairly simple and common. But the key questions are:**
- **Do we have the knowledge**
- **When do we admit/ recognize we do not have it?**
- **Can we avoid getting to this point of needing to do root cause analysis?**
  - **Do your homework – and manage risk**
    - **Or instead of risks, what about "things that could mess someone else up, but I should be ok with…"**
- **Once we find it, how do we make sure it does not happen again? SPC…**

# Questions

- **If you have questions or thoughts, feel free to share them with us**
  - **651-230-3861**
  - **Perry@PerrysSolutions.com**
- **If interested, email us to be on our quarterly newsletter where we share recent trends and learning.**
  - **They are all archived on our publications page**