Sensitivity Analysis:

Understanding performance issues in product development

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WHY SUNRISE

Privately Held Since 1991
Executive Management actively involved in day to day operations. Culture based on assumption of positive intent

Deep Domain Expertise
Infusion, Imaging, Cardiovascular, IVD, Robotics, Drug Delivery

Total Product Development
User Research, Sys Engineering, Project Management, HF, ID, SW, EE, ME, Optical, Quality and Test

Best Fit Design and CM;
Strategy, DFM, Design Transfer Process and Support

Size, breadth and depth of the team
80+ employees; deep medical device development expertise

Flexible Service Offerings
Complete product life-cycle (PD, Eng. Services, Consulting, Support)

Not meeting quantitative performance requirements

- Accuracy too low
- Repeatability too low
- Image resolution not consistent
- Machine Learning Classifier performance too low
- Response time too variable

There’s a BIG Problem

- The multidisciplined development team gets to work
- They look for root causes

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There’s still a BIG Problem

- Everything Matters
- Whose Fault is it?

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The Goal

- Wisdom: Is knowing what to focus on and what to ignore

An Example

- Example: IVD device
  - Not accurate or repeatable enough

The Problem

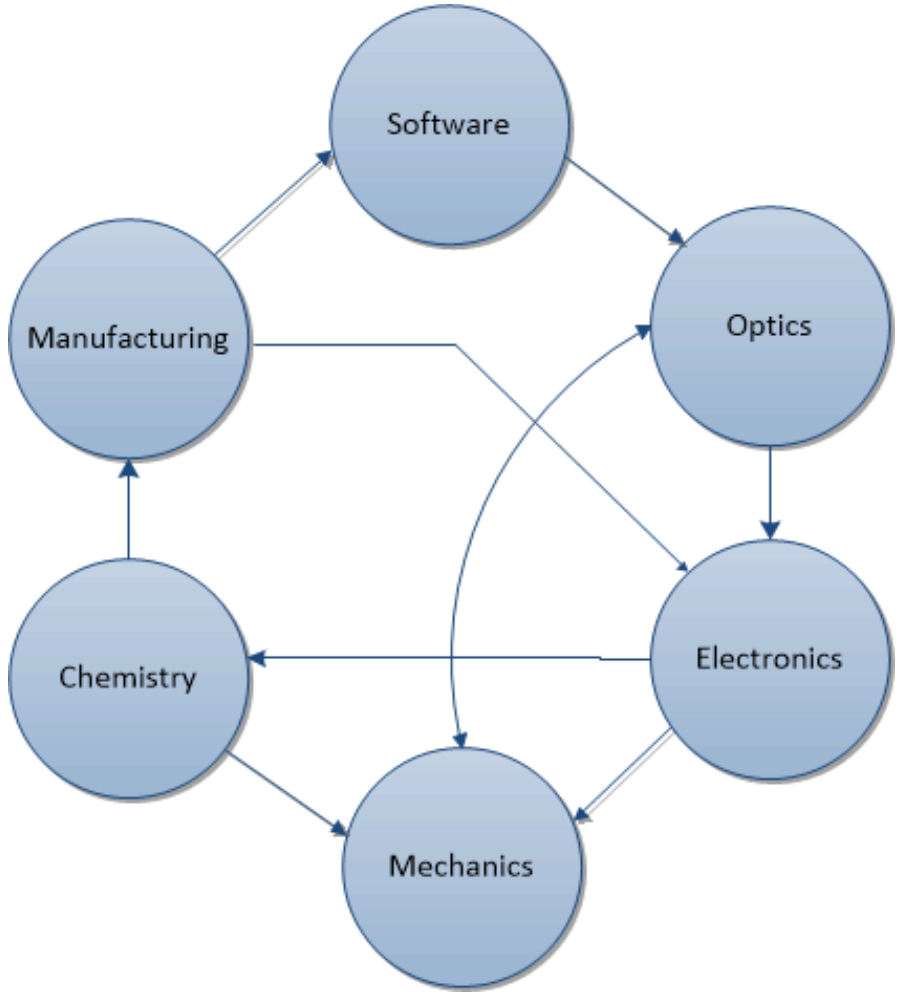
- Example: IVD device: Not accurate enough

- SW thinks its the optics(because the stray light affects the result) , Optical Engineer thinks its the chemistry (different lots give different results), Chemist thinks its the Electronics, who thinks it’s the mechanics, who thinks its manufacturing, who thinks it’s SW.

Systems Engineer

The Problem

- Signal Processing
- Optics
- Calibration
- Electronics Noise
- Lot to Lot disposable variation
- Intra Lot disposable variation
- Pipette accuracy
- Temperature
- Signal Processing
- Position Tolerances
- Vibration



What To Do?

- The systems engineer knows that all these things affect the result.
- But what to do and what not to do?

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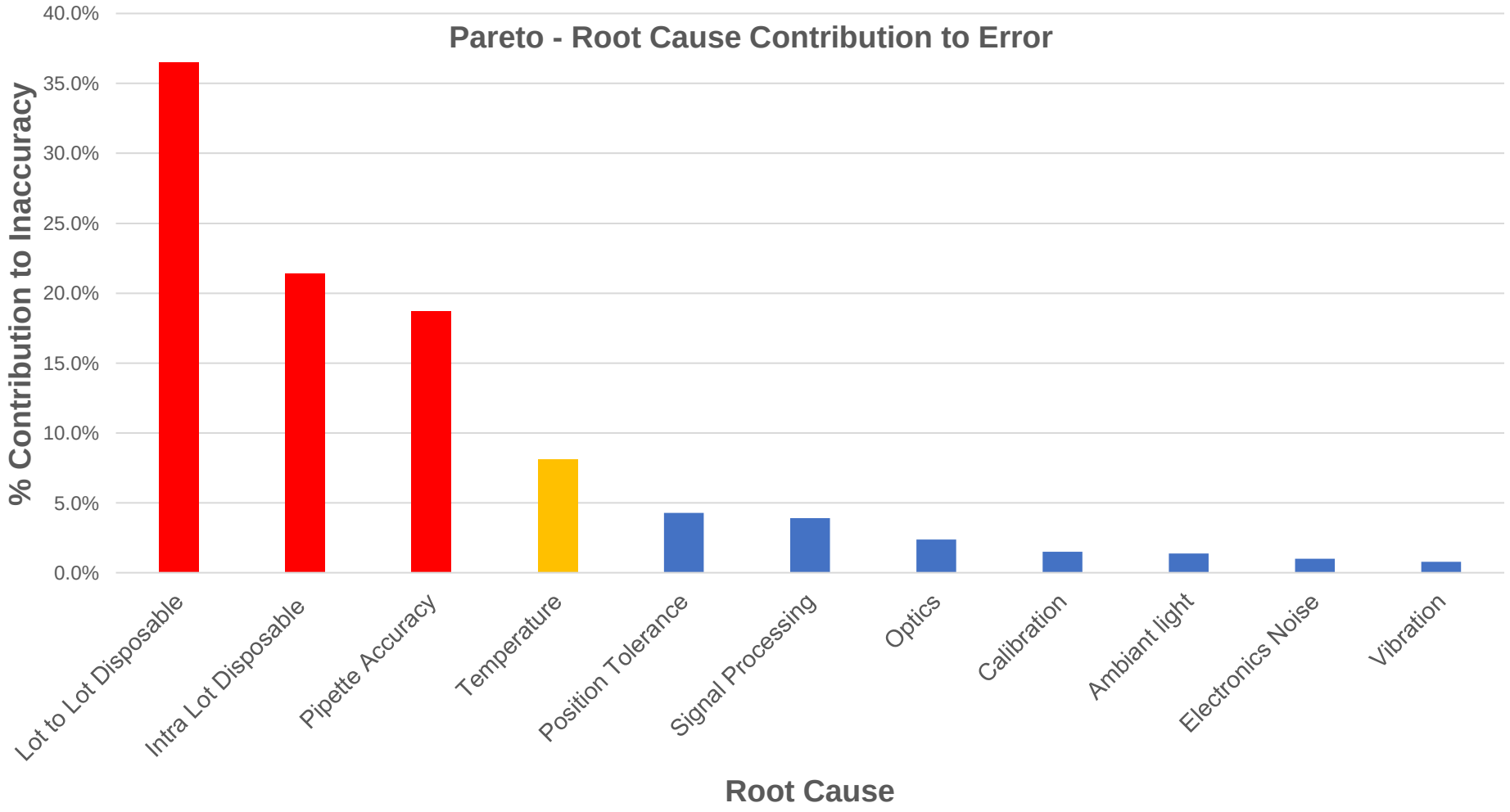
The Right Question

- The systems person knows that all these things affect the result. But what to do?
- A good question is worth three answers - *Spend more effort making sure you're answering the right question!*
- The question isn't what matters. It's how much it matters

What to Work On

- But what to do?
- A good question is worth three answers
- The question isn’t what matters. It’s how much it matters.
- Then what to work on can be determined.

Sensitivity Analysis: A way to quantify how much root causes matter.

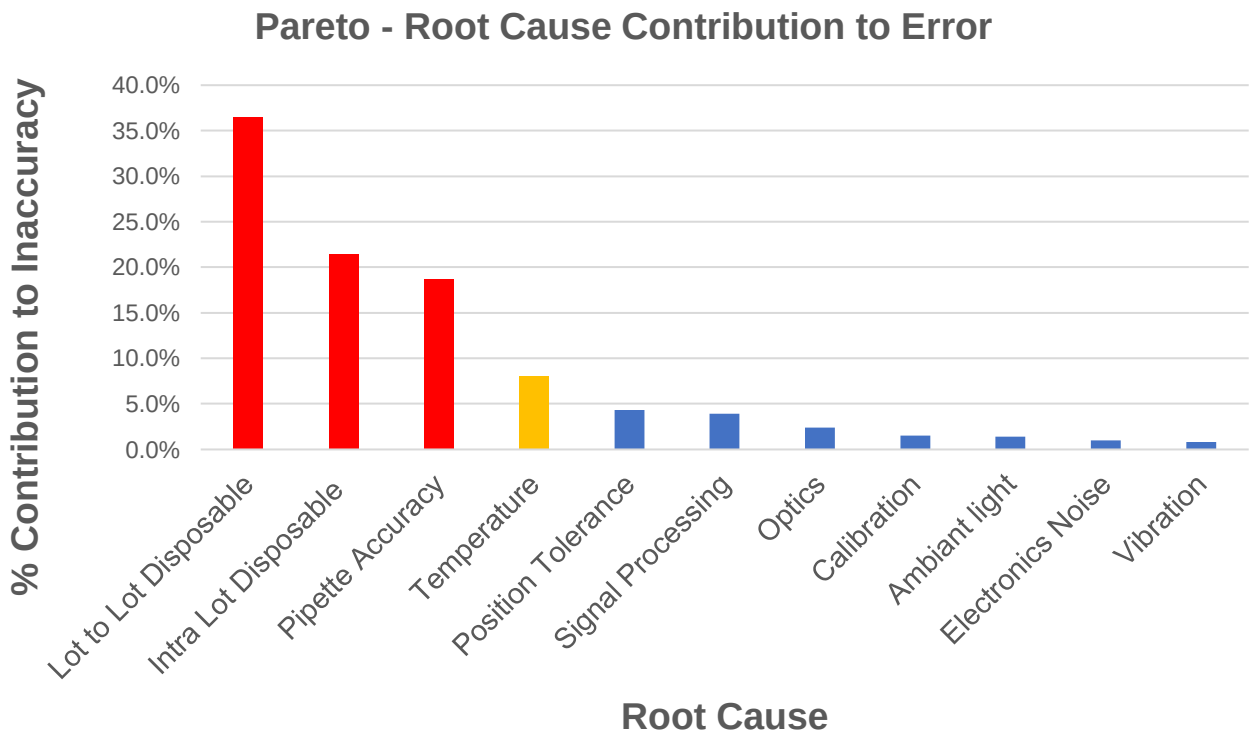


Only after you know what to work on

- Start working on solutions
- Most people jump to solutions too quickly

The Process: Two starting points

- List every variable that could matter
- Determine your figure of merit



Analytical vs. Experimental

Analytical

- Complete isolation of variables
- Many tests
  - High resolution
  - Larger range
  - Statistically significant
- Limited to the model
- Requires the model to be used correctly
  - Initial conditions
  - Constants are right
  - Distributions are close
  - Models important variables (not overly simplistic)

Analytical vs. Experimental

Experimental

- Variables are mixed unless carefully controlled
- Labor intensive
- Usually small(er) sample sizes
  - Does not cover the real life range
- Shows real life results not included in the model (validation)
- Need supplies
  - Can be few available early in the project
  - Can be hand made and not representative of manufacturing
  - Need a lot of them

Isolating the effect of each single variable on the figure of merit

- Find a way to isolate the effect of each variable:
  - This can be analytical or experimental
- Perform a “perturbation analysis” turning one Knob at a time and see how it affects the outcome (figure of merit)
- Try different amounts of turning each knob. How much is the figure of merit affected with small changes, big changes?
- Work on this until you get a feel for how much the inputs change the output.

Reading the results

- Perturbation Analysis
- Monte Carlo Analysis

Knowing how the combination of variables affect the figure of merit

- Monte Carlo Analysis
  - Distributions – Gaussian, biased, flat, binomial, Poisson
  - Limits
  - Reading the results
  - Assigns randomly selected parameters into the model in many combinations to get an expected statistical distribution of outcomes
  - Set different limits to quantify how it affects the outcomes STATISTICALLY

Conclusions

- Monte Carlo Analysis
- Good Sensitivity Analysis provides deep understanding of system behaviors
- It takes an investment of time and resources
- Good for systems level thinking
- Takes practice
- Provides clear direction
- Reduces wasted effort
- Reduces project and organizational paralysis, noise, finger pointing and ambiguity

Questions?

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Thank you!

Every Great Project Starts With A Thoughtful Conversation

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