



TEN SECRETS OF A SUCCESSFUL NONCLINICAL STATISTICIAN

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AMGEN[®]

Pioneering science delivers vital medicines™

I AM ON MY THIRD CAREER IN APPLYING MATHEMATICS & STATISTICS TO SOLVE BUSINESS PROBLEMS

- **1980 – 1992** **Scientific Analyst in the US Air Force, Executive Officer and Associate Professor of Mathematics at the USAF Academy**
- **1993 – 2000** **Led an expansion consulting group focused on Statistical, Technical and Information Systems in the Medical Device & Pharmaceutical Industries**
- **2000 – Present** **Led Site & Corporate Quality Engineering, Operational Excellence & Quality Data Sciences groups at Amgen, Inc.**

THE MOST SUCCESSFUL NONCLINICAL STATISTICIANS HAVE COMMON TRAITS



The following are ten traits worth sharing

BUILD A TRACK RECORD OF SUCCESSES

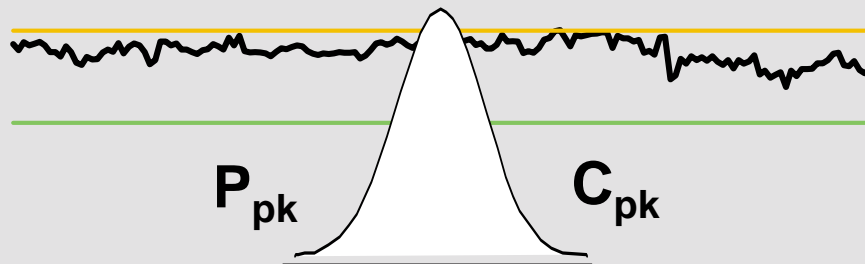
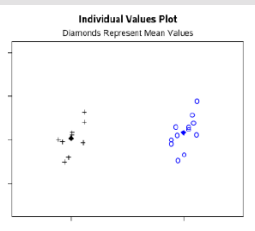
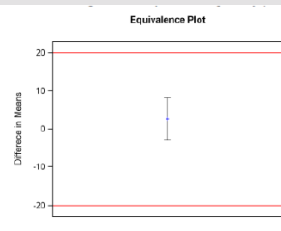
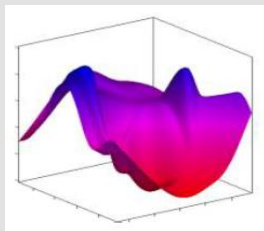
- **Competently complete required analyses**
- **Be as flexible & creative as possible**
- **Go the “extra mile” for your clients**
- **Become the go-to problem solver, even if it isn't exactly a statistical problem**
- **Be a key team member in solving a significant business issue**
- **Whether you know it or not, you're building a reputation**

EDUCATE OURSELVES ABOUT THE BUSINESS AND WHAT THE BUSINESS NEEDS FROM US

“We aspire to be the best human therapeutics company. We will live the Amgen Values and use science and innovation to dramatically improve people’s lives.”

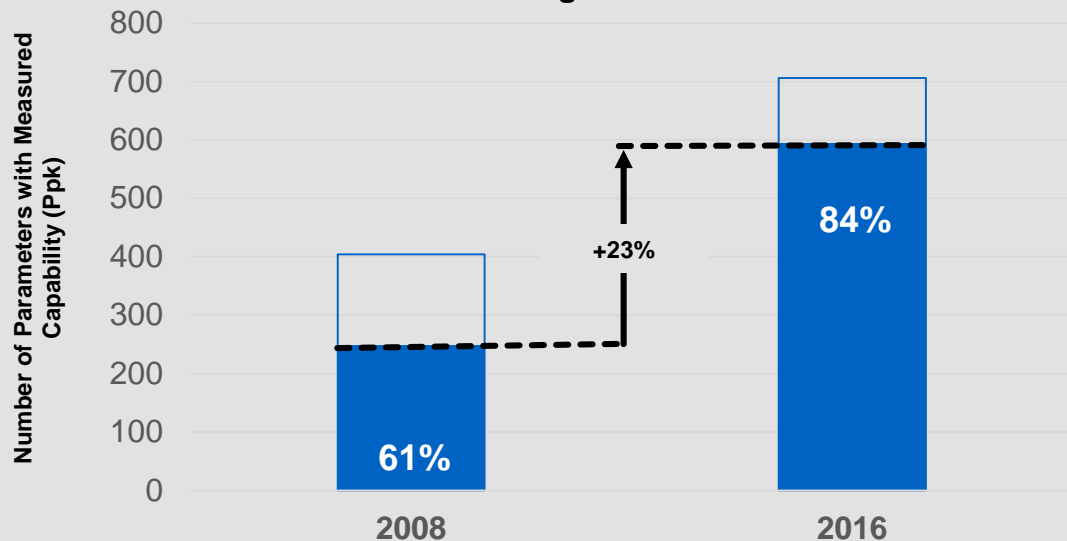


We can apply our expertise to help our companies achieve their aspirations



WE CAN HAVE A SIGNIFICANT IMPACT ON OUR COMPANY'S GOALS AND ASPIRATIONS

Percent of Product Parameters at or above 6 Sigma Performance



Improvements to analytical methods, manufacturing processes and Amgen's in-process control strategy account for most of the increase.

The bottom line is that more processes operating at a Six Sigma level result in fewer errors and more effective use of resources.

Quantitative problem solving is also integral to process improvements and investigation resolution

SPEAK SIMPLY -



After a particular process improvement was implemented, a set of samples were measured. The average result was 1280mg and the variability (standard deviation) was 110mg. Which conclusion can be better interpreted by non-statisticians?

- The result was not inside the predetermined acceptance region and we fail to reject the null (H_0) hypothesis.
- The data collected after the improvement do not provide enough evidence that the process actually improved.

PARTNER WITH OUR CLIENTS



**Our world is full of
numbers, analyses
and graphs**

**Our clients live on
completely
different planets**

ENSURE CLIENTS UNDERSTAND THEIR ROLE IN ASSESSING STATISTICAL SIGNIFICANCE

Statistical significance:

Signal > Noise

Influenced by:

Small s Large n

Practical importance: Up to our clients – based on the change detected in results (signal):

- What is the impact to a product or to our patients?
- Does this simplify or add complexity to a process?
- What is the regulatory impact?
- What is the return on any investment?
- Will this lower costs for the company and patients?
- Does this create a competitive advantage?

COMMUNICATE, COMMUNICATE, COMMUNICATE



Share progress

Identify roadblocks

Teach others

Be likeable



IDENTIFY OPTIONS FOR OUR CLIENTS

How many samples do I need to ...?

Sample Size Choices				
Historical Average:	1280 mg			
Historical Variability (Standard Deviation in mg)	110 mg			
		Chance of correctly concluding that the process is improved		
		99%	95%	90%
Improvement in the average result that can be detected with the sample	20	164	82	50
	40	41	20	12
	60	18	9	6
	80	10	5	3
	100	7	3	2
	110	5	3	2
	120	5	2	1
			1%	5%
		Risk of incorrectly concluding that the process is improved		

ASK CLARIFYING AND/OR PROBING QUESTIONS

- A clarifying question is one focused on gathering more facts - the answer is usually quick, short & simple
- A probing question is one which requires more thought and is often an opinion - the client may pause before answering

LISTEN TO OUR CLIENTS

- “Listen” and “silent” have the same letters
- Listen to understand the request for help
- Summarizing what was heard is important
- Quite often the request is not the request



"The most important thing in communication is hearing what isn't said" --Peter Drucker

THE TEN SECRETS OF A SUCCESSFUL NONCLINICAL STATISTICIAN

Build a track record of successes

Educate ourselves about the business and what the business needs from us

Speak simply

Partner with our clients

Ensure clients understand their role in assessing statistical significance

Communicate, communicate, communicate

Identify options for clients

Ask clarifying and/or probing questions

Listen to our clients

Nonclinical statisticians are a **SPECIAL** asset. We should continuously work to improve important soft skills of those staff members.