The use of Six Sigma on the Pharmaceutical Industry

Orlando Lozada

Lean-Six Sigma Black Belt

Pfizer Puerto Rico

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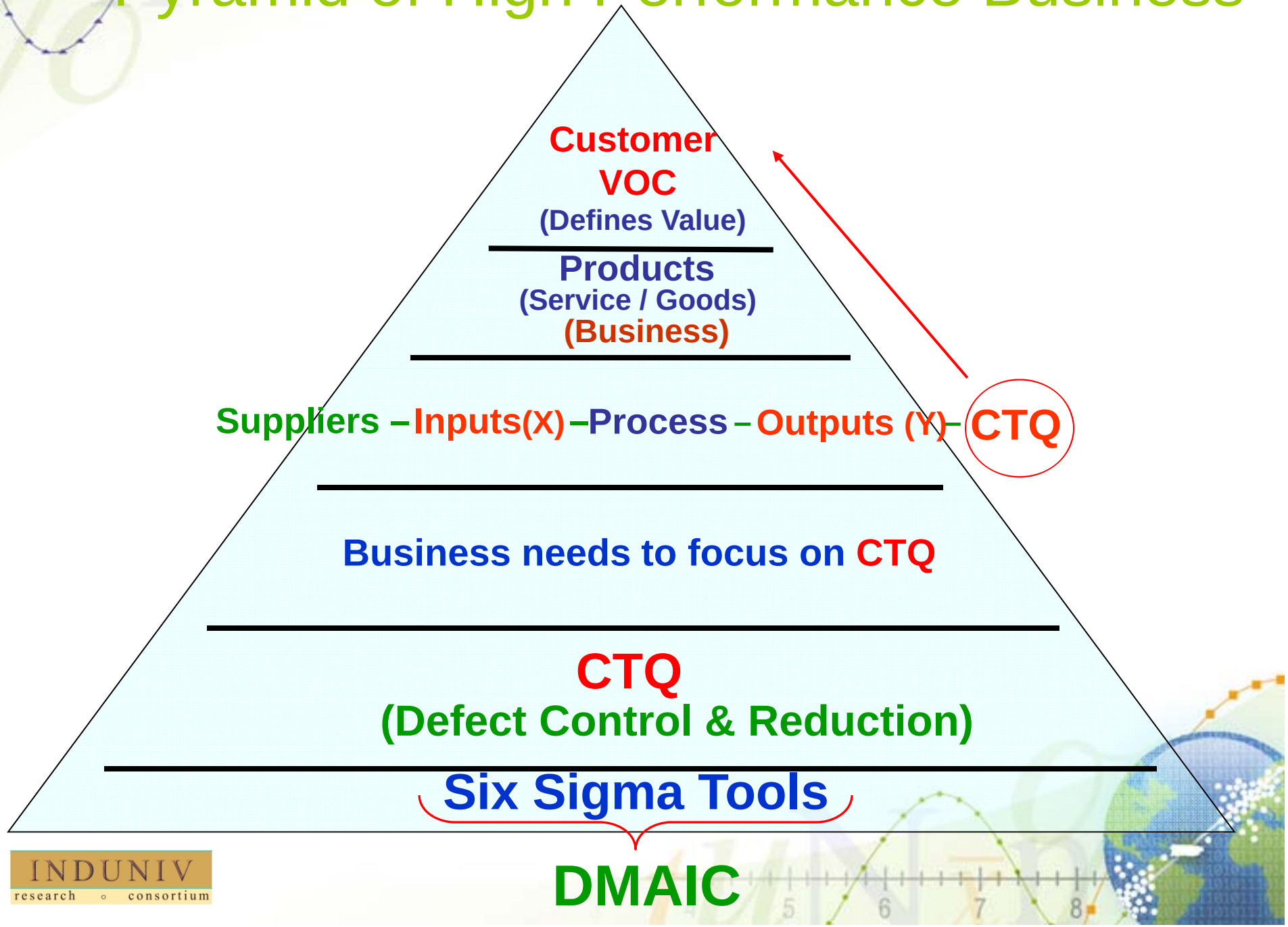
Pyramid of High Performance Business



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DMAIC:
Universal Problem -Solving Methodology
5 Logically Linked Steps

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DMAIC Objective

Practical (Problem / Opportunity)

↓

Statistical Problem (6-sigma tools)

↓

Statistical Solution (6-sigma tools)

↓

Practical Solution / Improvement

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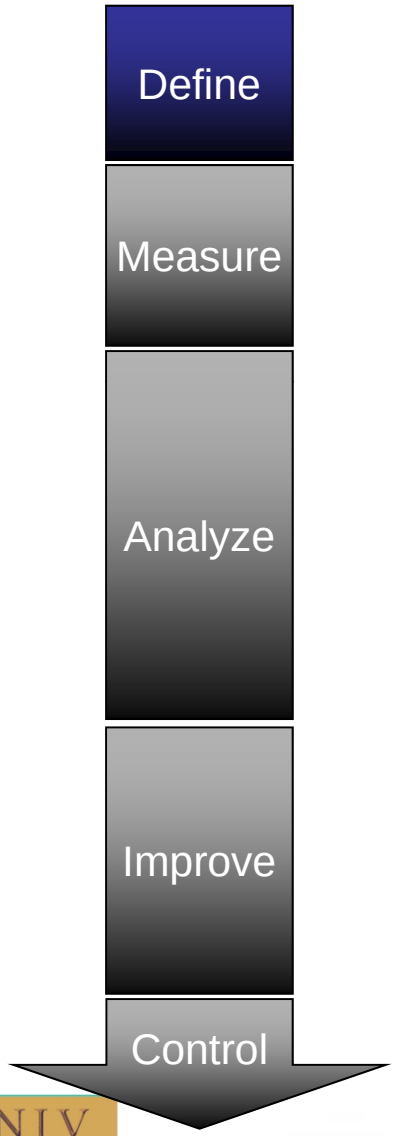
1. The Define Phase



- **Project Charter**
- **SIPOC Analysis**
- **Voice of the Customer**

- Data Collection & Operational Def.
- Data Measurement Tools: Funneling, Sampling, Minitab, Gage R&R, Patterns, Stratification, Process Capability

- Data Analysis Tools: Cause & Effect Diagrams, Stratification, Hypothesis Testing, Regression Analysis, Design of Experiments

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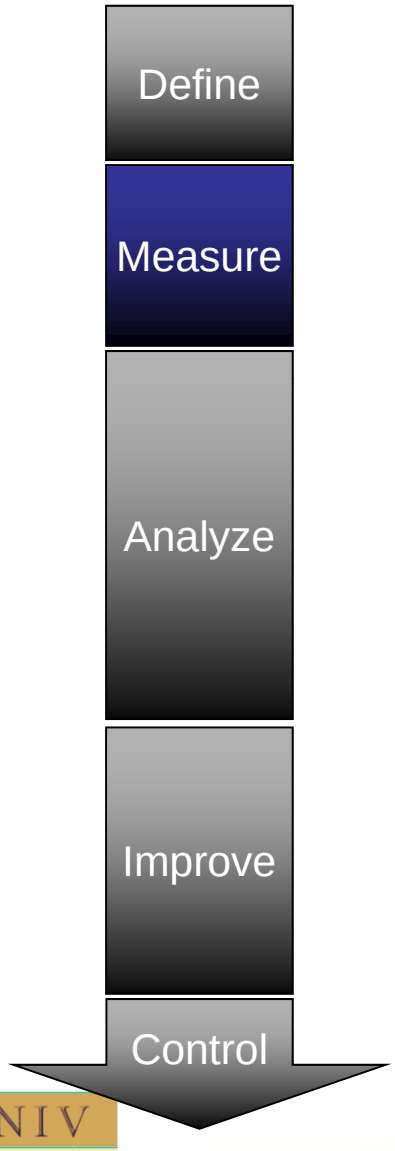
2. Measure Phase



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Data Collection Plan

What is the data trend?

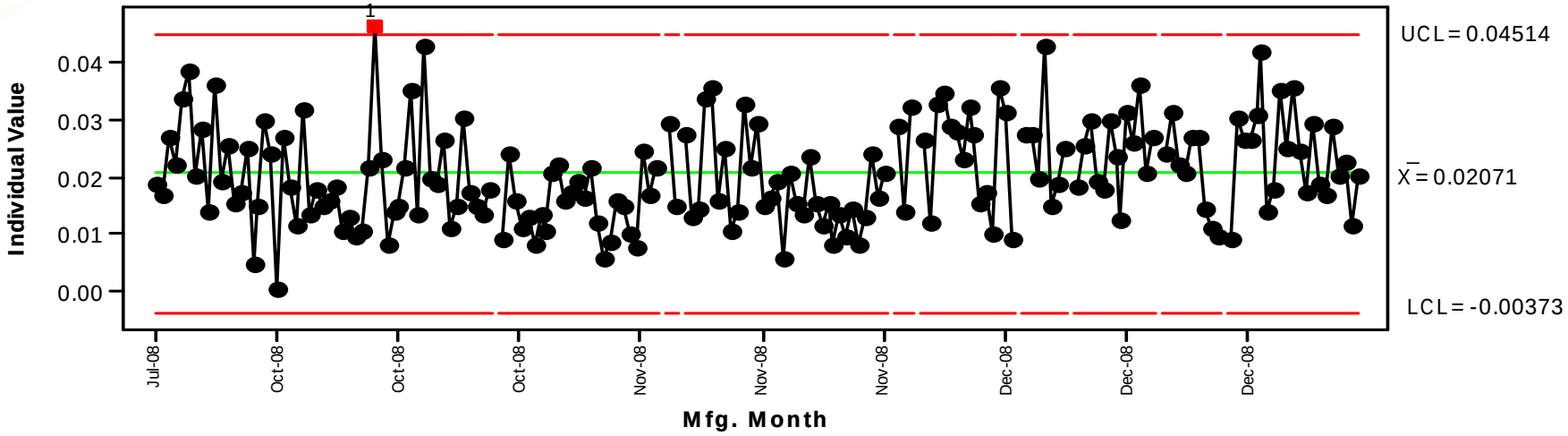
Does the data indicate any particular distribution?

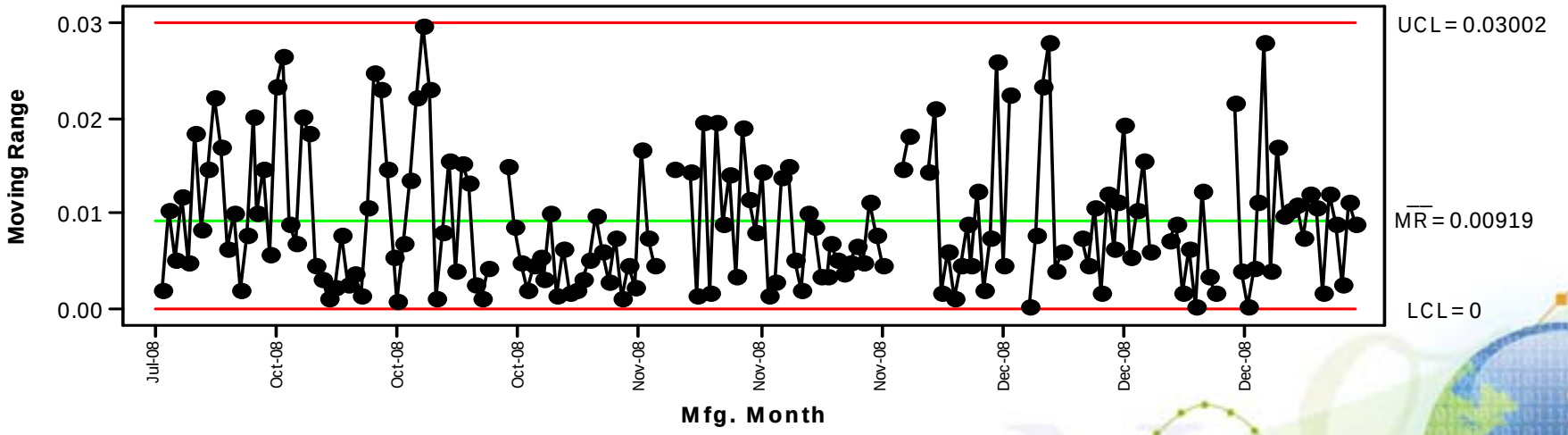
Is there any outlier in the available data set?

Data			Operational Definitions & Procedures		
What	Measure Type, Unit of Measure	Data Type	How Measured	Related Conditions	Sampling Notes

I Chart of Measurement vs date

Capsule Filling Date: July to December 2008





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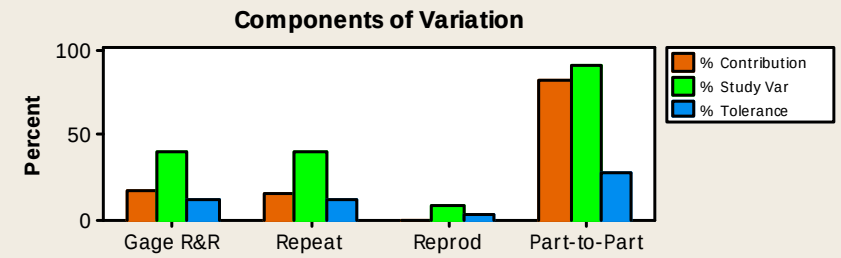
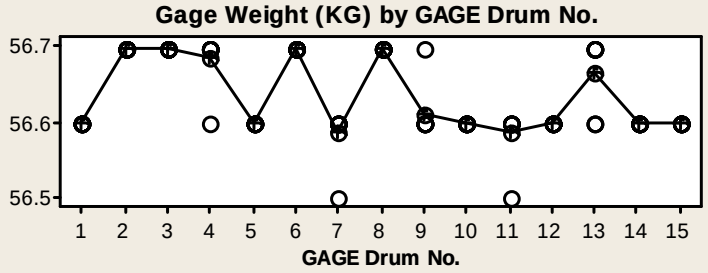
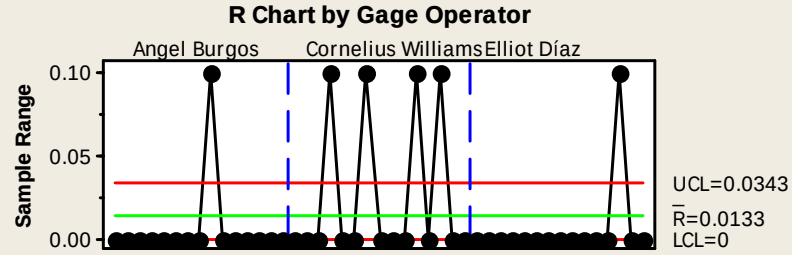
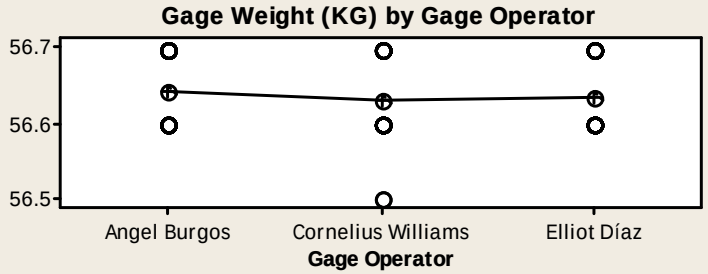
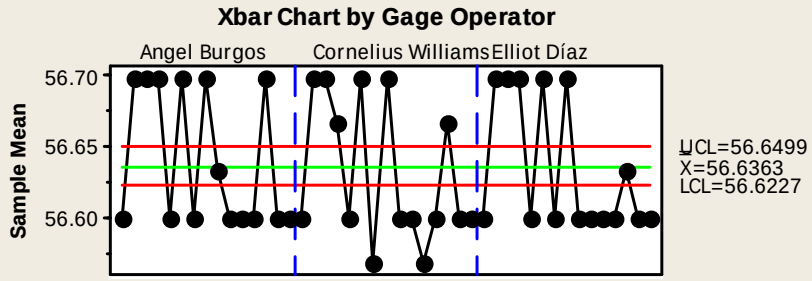
Gage R&R Analysis

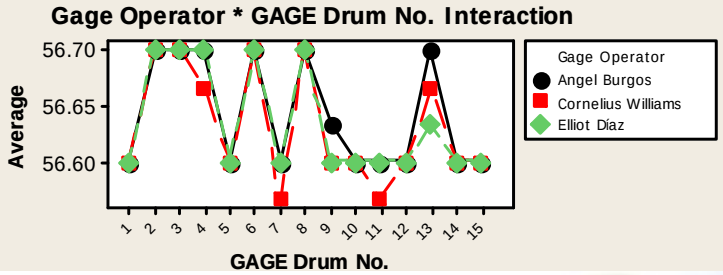




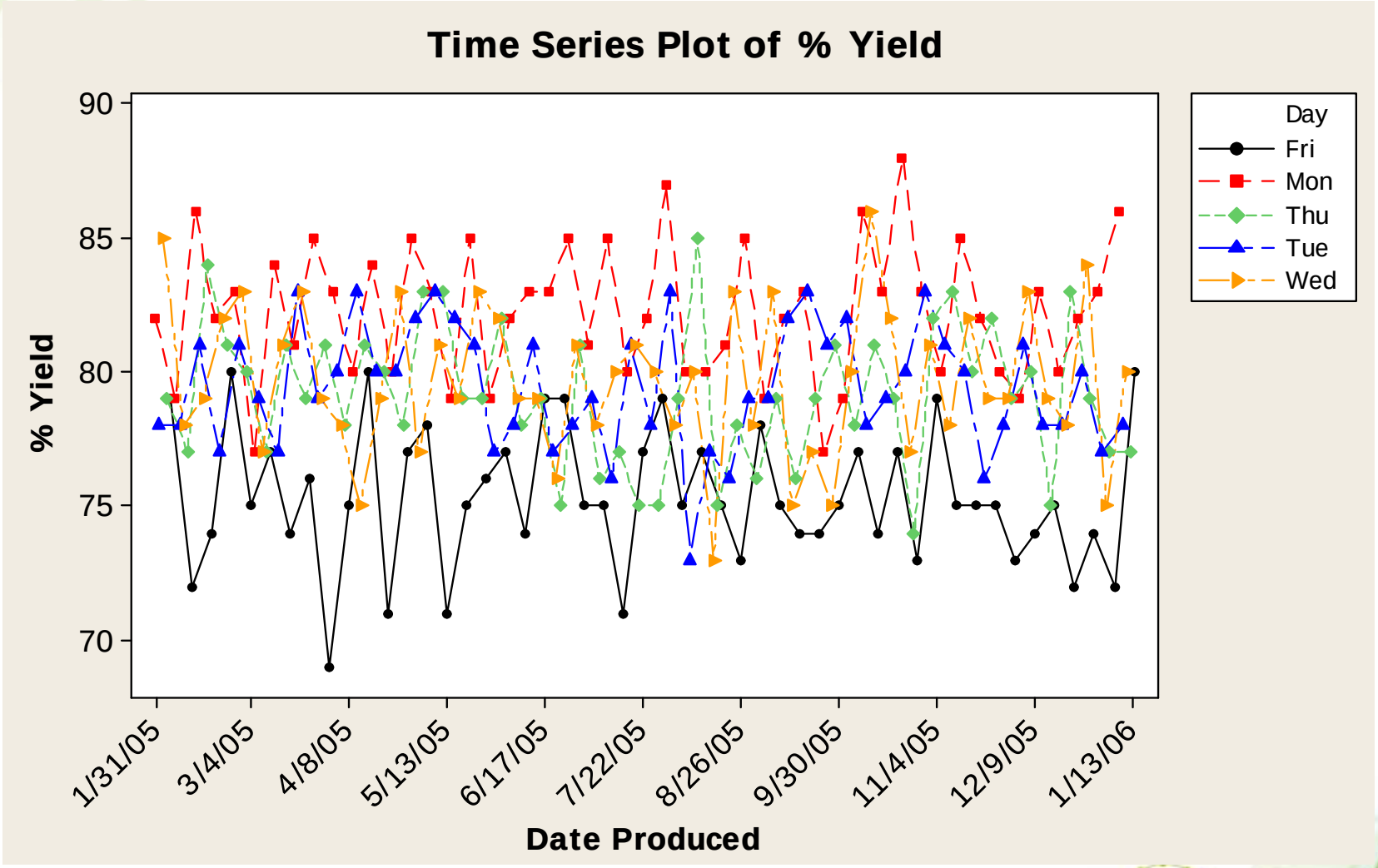








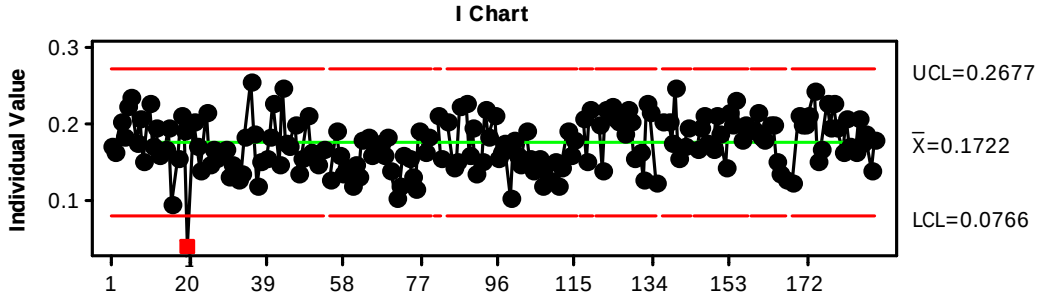
Stratified Time Series Plot

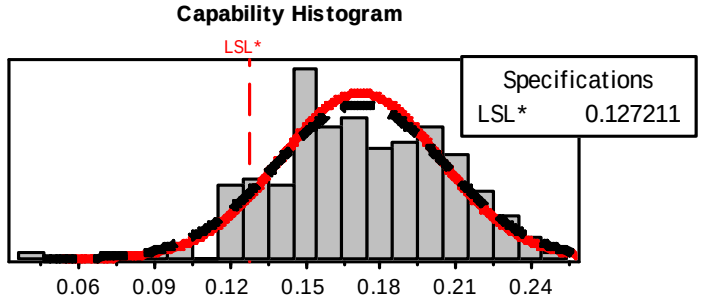


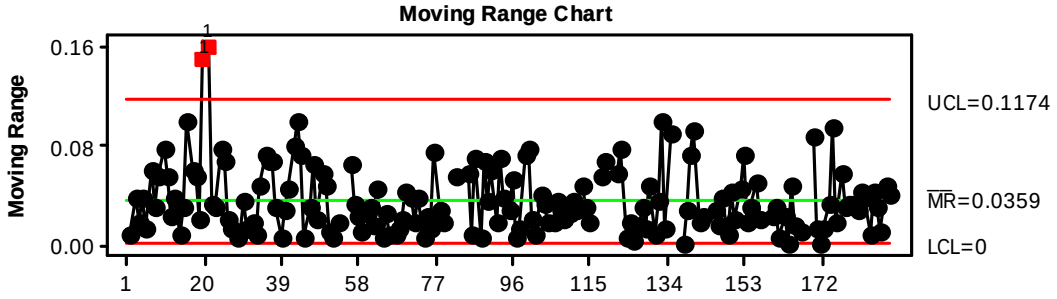
Process Capability Report

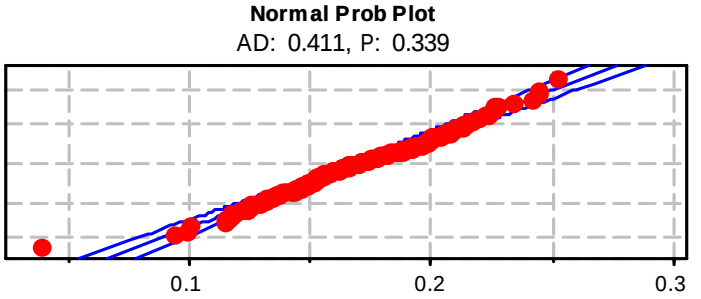
Using Box-Cox Transformation With Lambda = 0.45

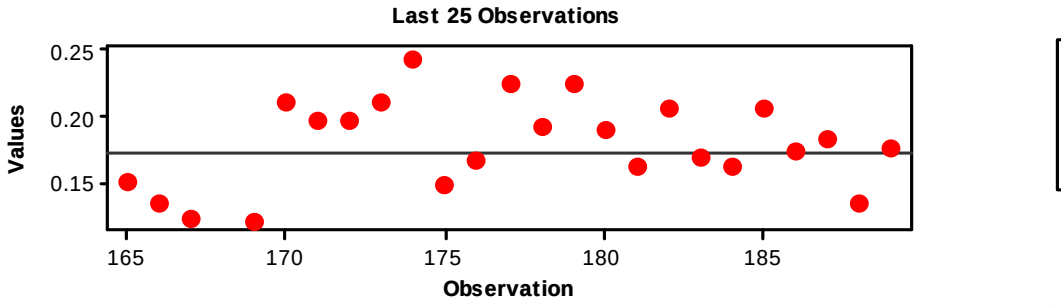
Capsule Filling Date: July to December 2008

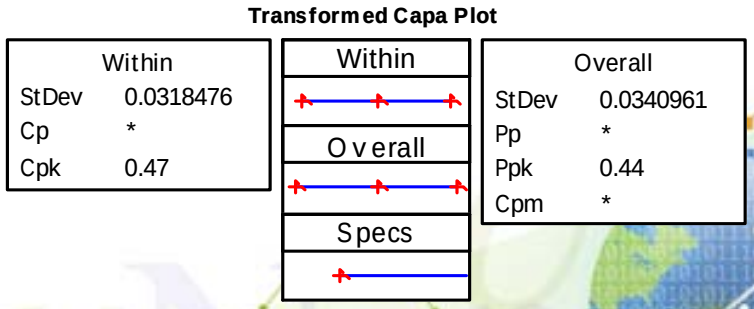












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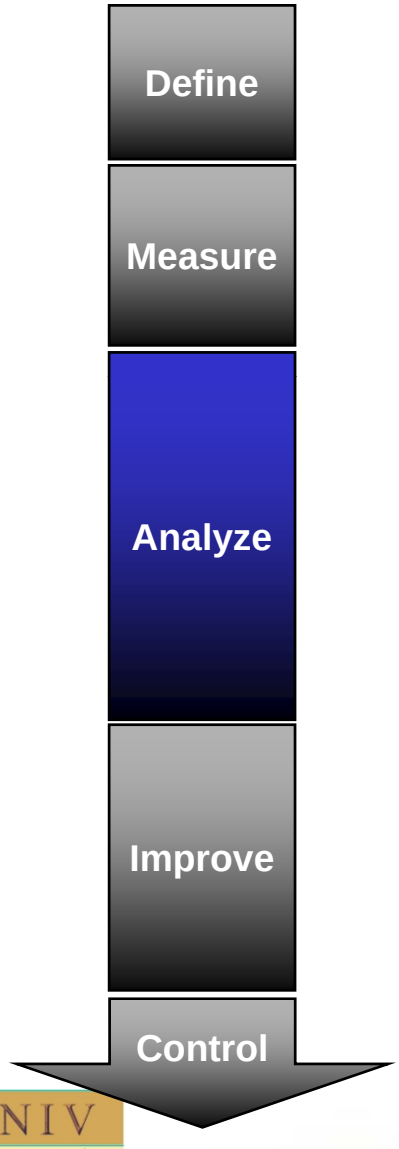
3. Analyze Phase



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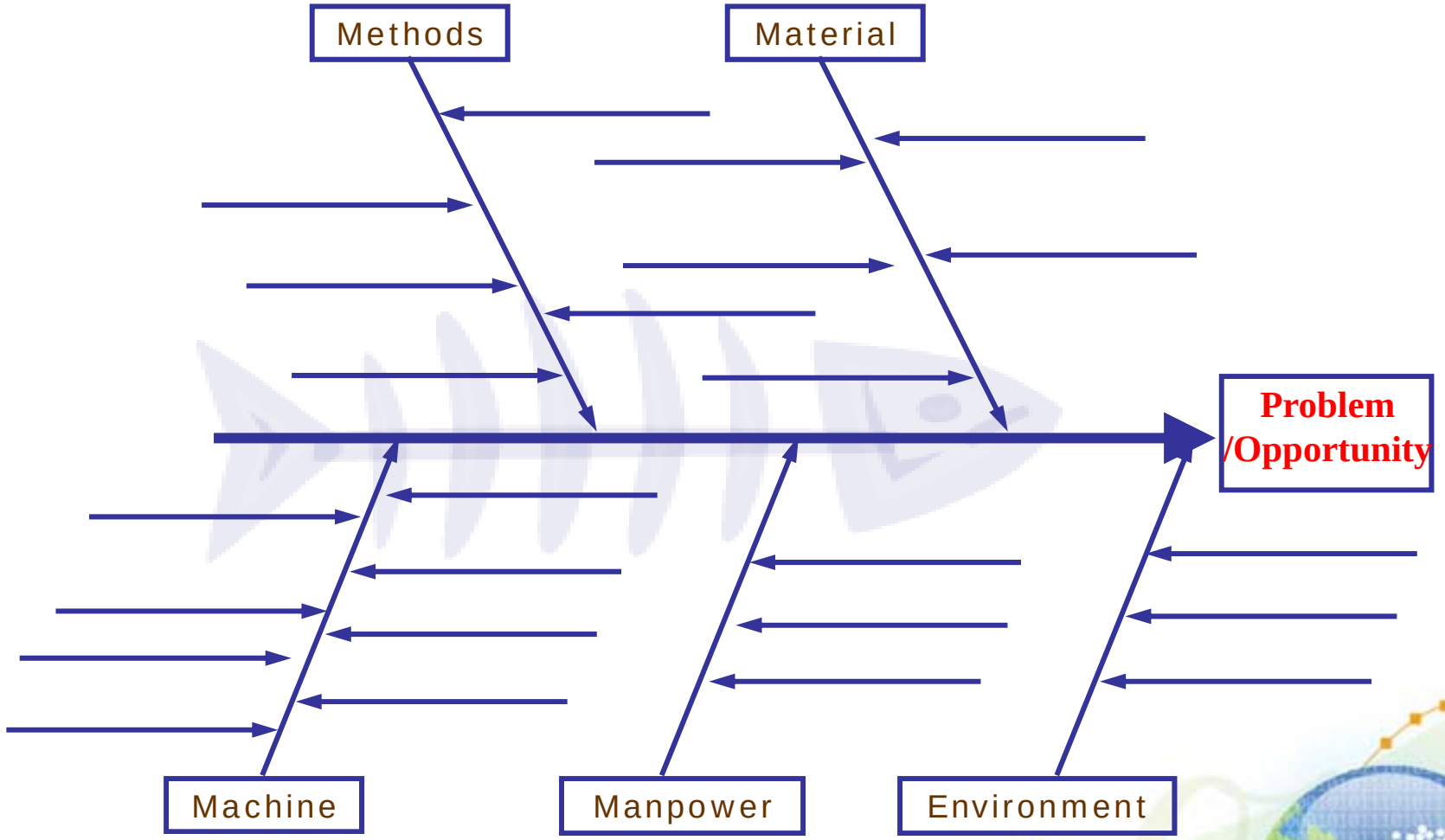
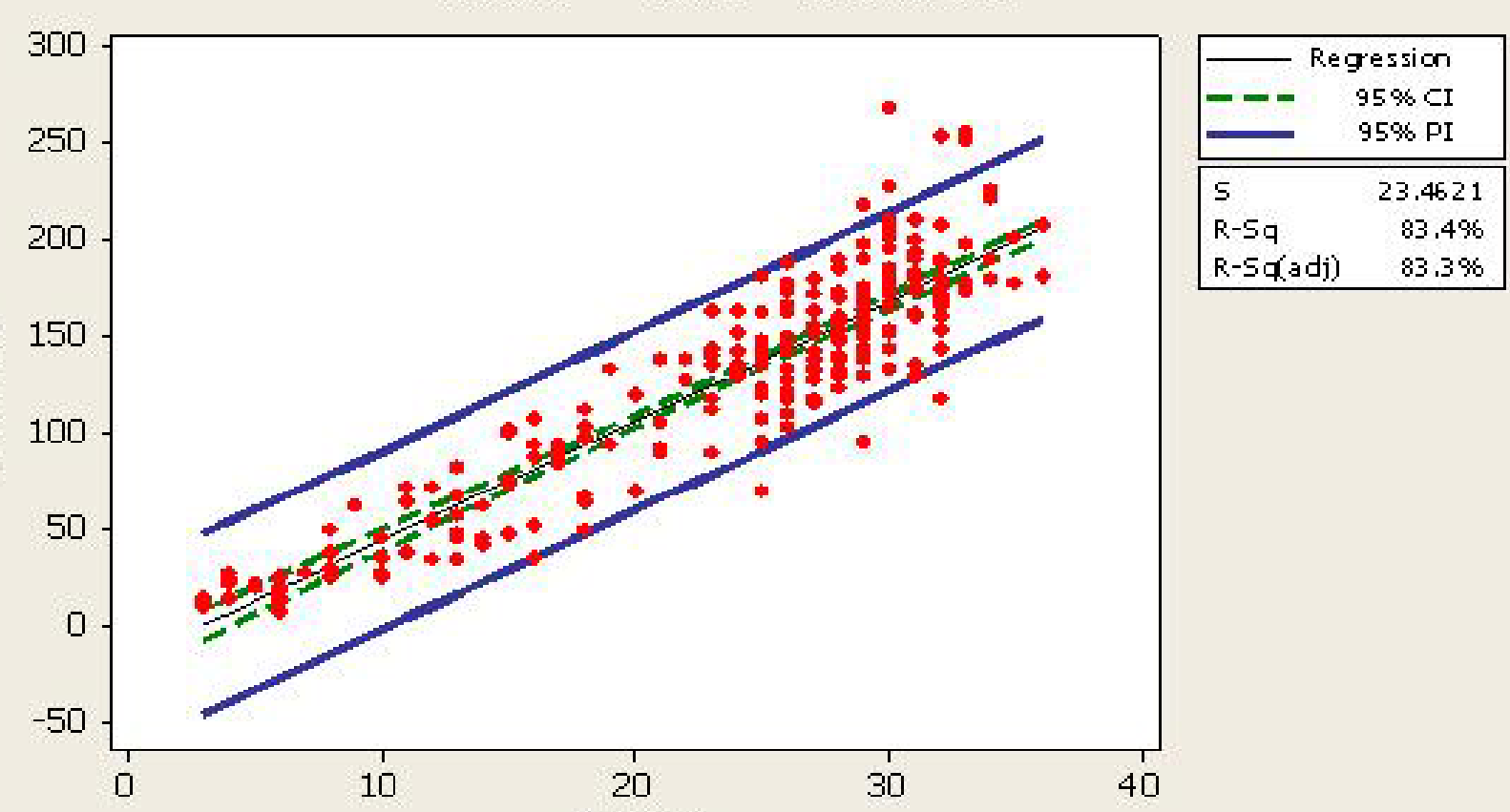
Cause & Effect Diagram



Regression Analysis

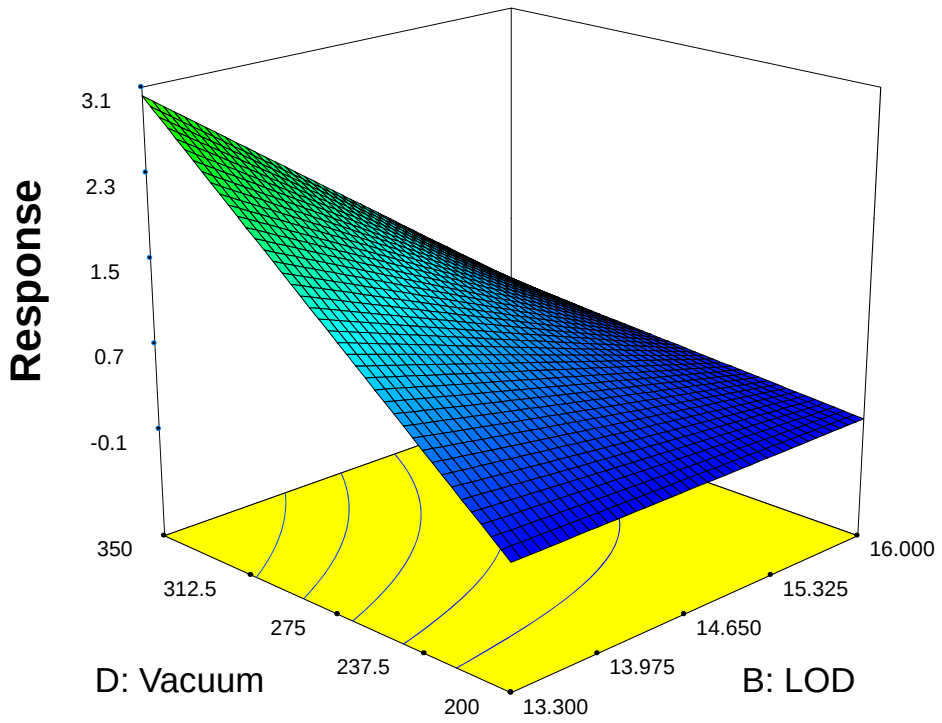


Experimental Design Results
Surface plot of Response vs. Two Variables

Design-Expert® Software
Transformed Scale
Sqrt(Response)
5.2915
0

X1 = B: LOD
X2 = D: Vacuum

Actual Factors
A: Thickness = 0.080
C: PH = 5.15



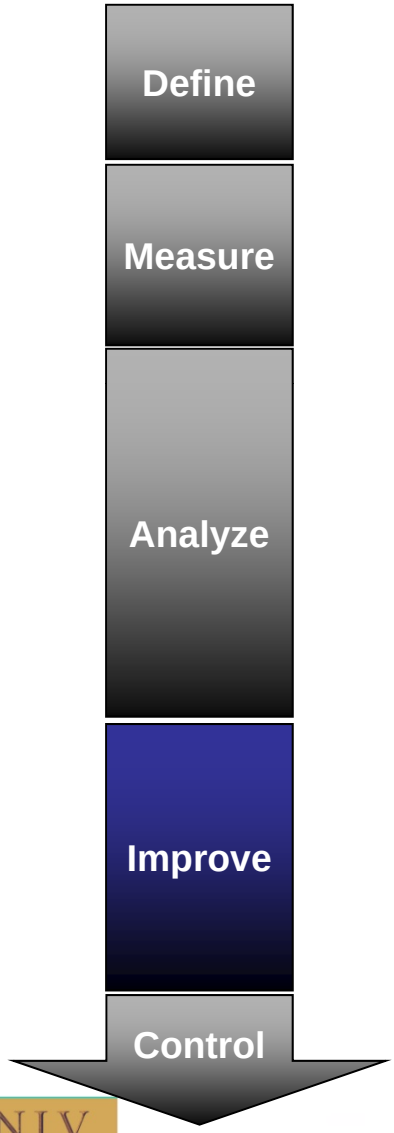
Hypothesis testing to demonstrate significance of Change

Two-sample T for Transformed data

Period	N	Mean	StDev	SE Mean
Before June_09	22	0.536	0.830	0.18
Post June_09	12	-0.655	0.939	0.27

Difference = mu (Before June_09) - mu (Post June_09)
Estimate for difference: 1.191
95% CI for difference: (0.516, 1.866)
T-Test of difference = 0 (vs not =): T-Value = 3.68 P-Value = 0.001 DF = 20

4. Improve Phase



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R&S

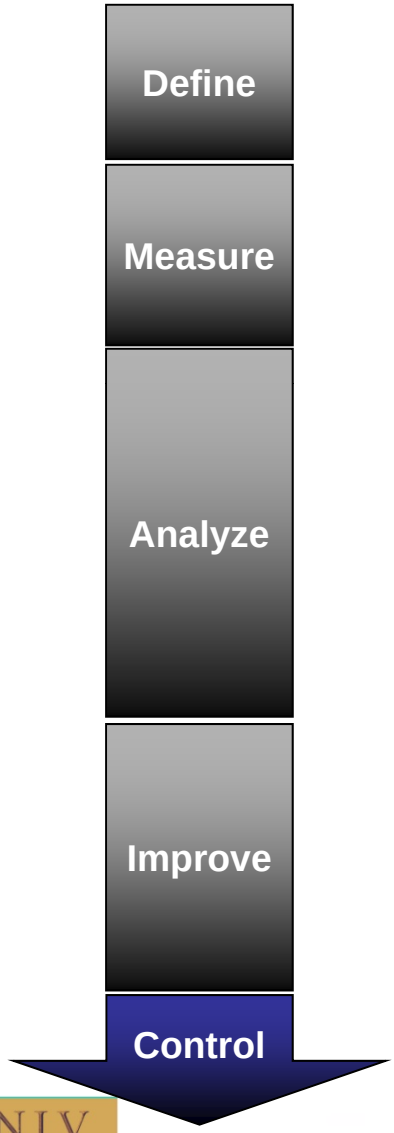
FMEA Assessment for Identified Solutions

Key Process Step or Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended
What is the Process Step or Input?	In what ways can the Process Step or Input fail?	What is the impact on the Key Output Variables once it fails (customer or internal requirements)?	How **Severe** is the effect to the customer? (1-not severe, 10 extremely severe)	What causes the Key Input to go wrong?	How **often** does cause or FM **occur**? 1-highly unlikely to ever occur,10 we expect it to happen all the time)	What are the existing **controls** and procedures that prevent either the Cause or the Failure Mode?	How well can you **detect** the Cause or the Failure Mode? 1-we have excellent controls,10-we have no controls or extremely weak controls	Risk Priority Number (SEV x OCC x DET)	What are the actions for reducing the occurrence of the cause, or improving detection?

Pilots

- Find flaws in the solution
- Improve the solution before full-scale implementation
- Find out if you are getting the results you expected.

5. Control Phase



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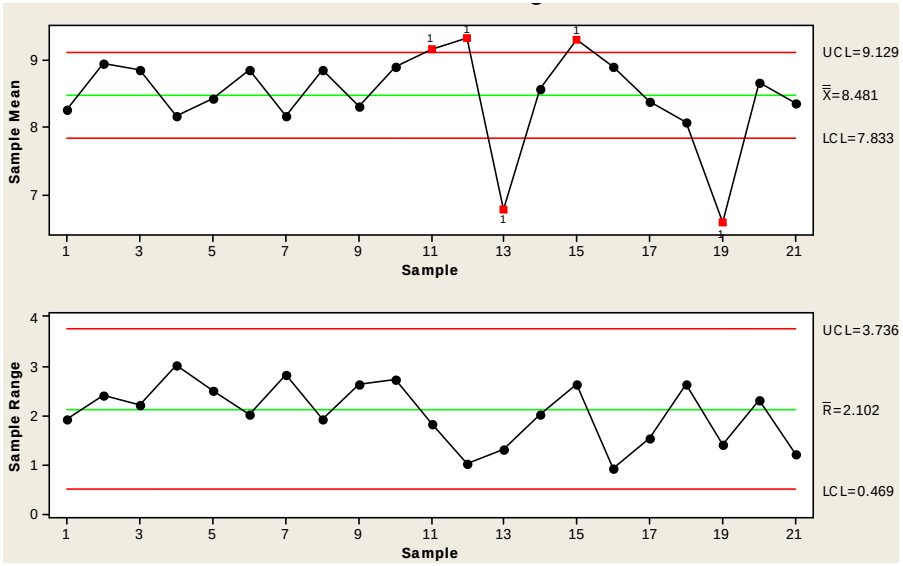
Define | Measure | Analyze | Improve | Control

Control Phase Results

Before Implementation: Non-stable process



After Implementation: Stable Process

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Six Sigma Projects Related to:

- Complaint Investigations
- Deviation Investigations
- Environmental Projects
- Laboratory Data / Specifications / Stability
- Lead Time Optimization
- Process Optimization
- Product Optimization
- Safety Assessments & Investigations

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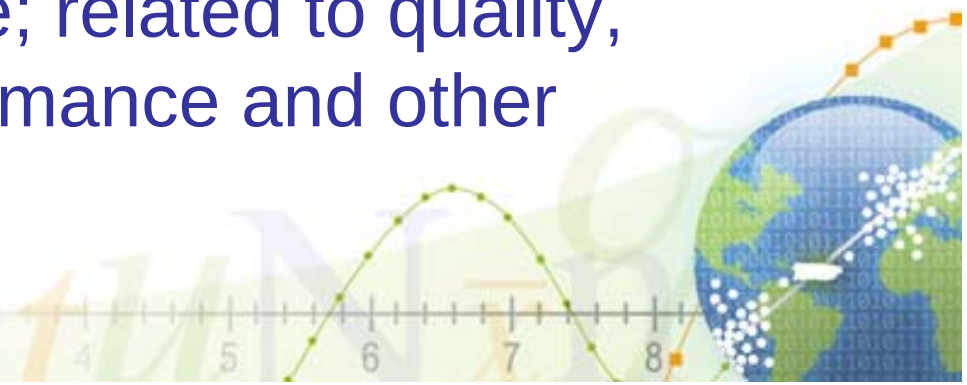
Summary

- 6-Sigma tools are embraced by a 5 logically linked steps, DMAIC, which enables tools understanding and proper use
- Each year hundreds of projects are completed using 6-sigma tools
- These projects add significant benefits to the business performance; related to quality, safety, process performance and other



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End

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