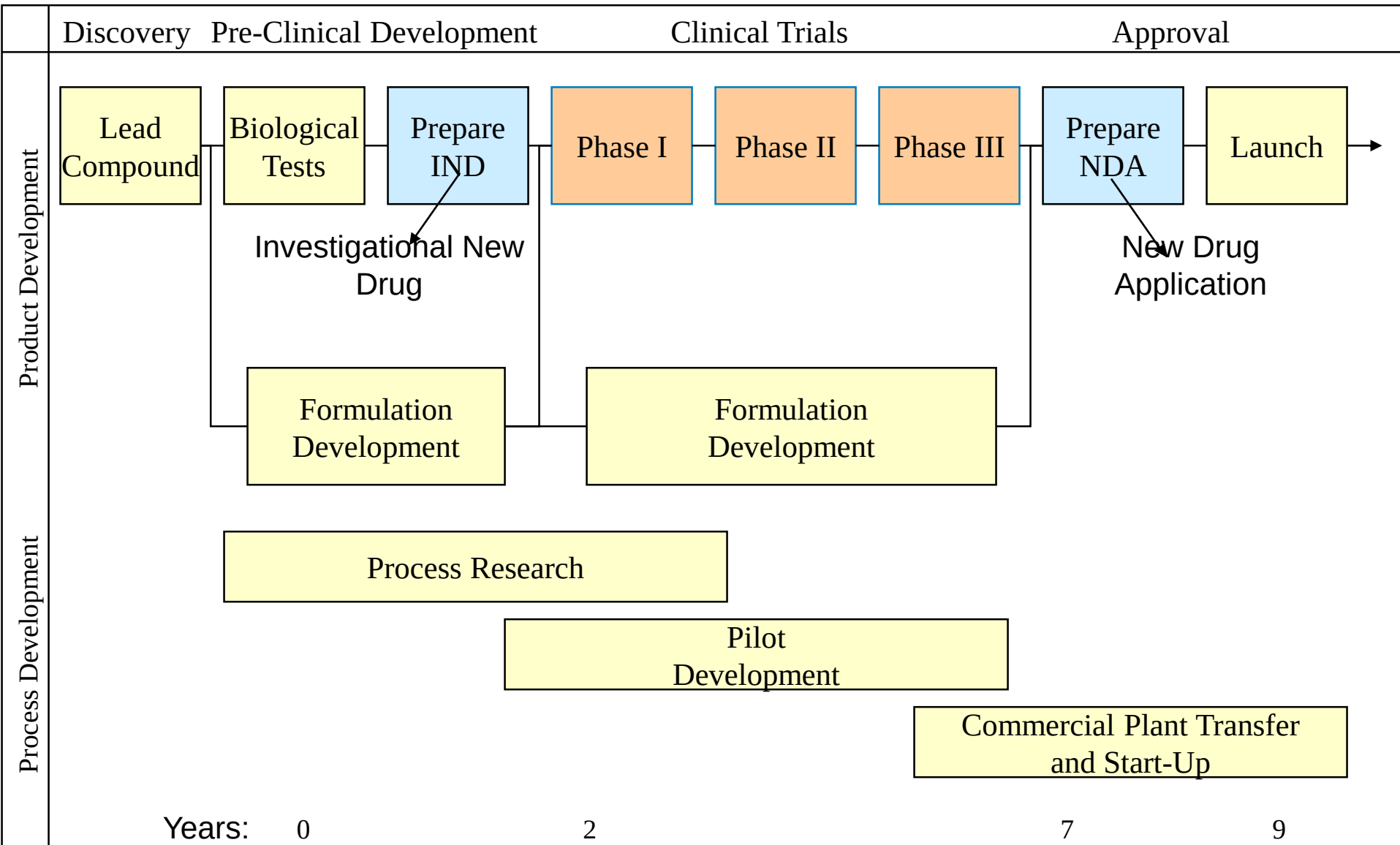


Accelerate Drug Development from Lab to Fab with Design & Analysis of Experiments



William Zhou
JMP Division, SAS Institute, Inc.

New Drug Timeline



Process Development

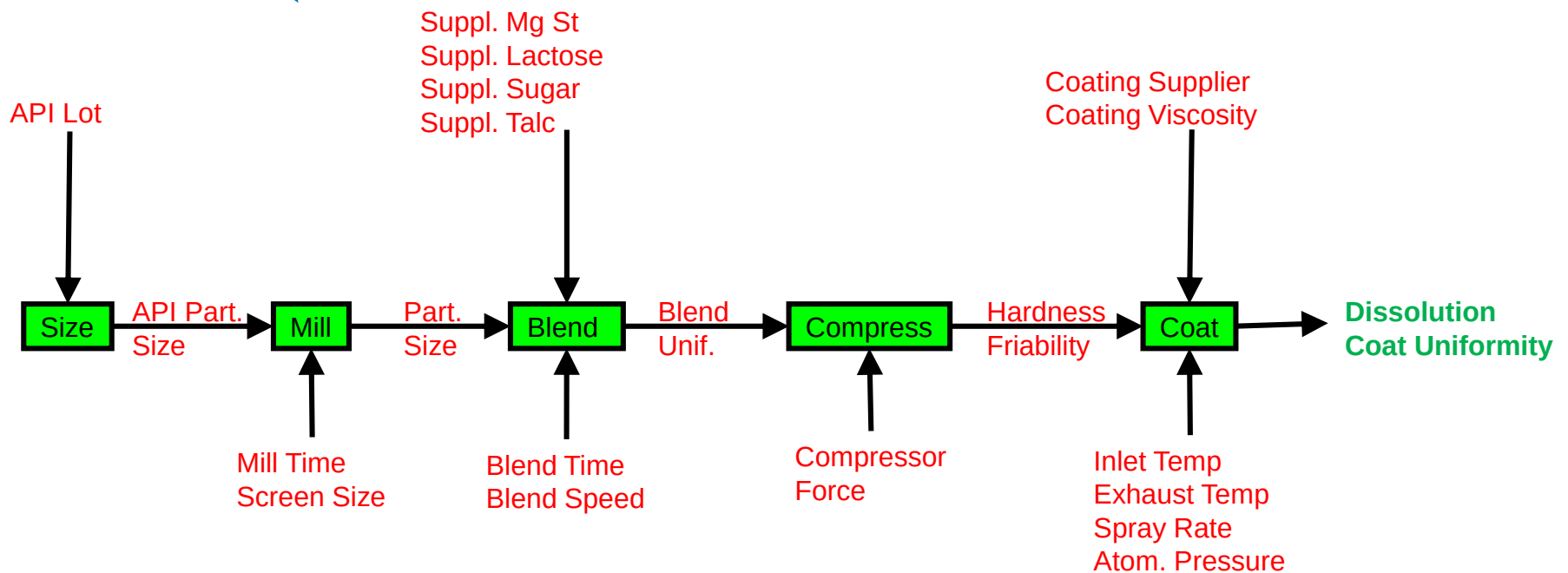
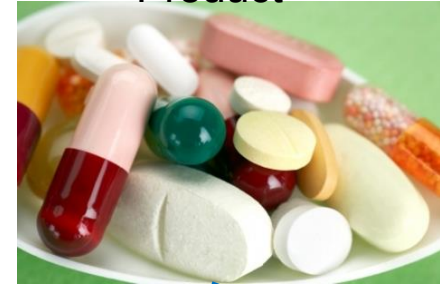
Starting materials



Active Ingredient



Drug Product

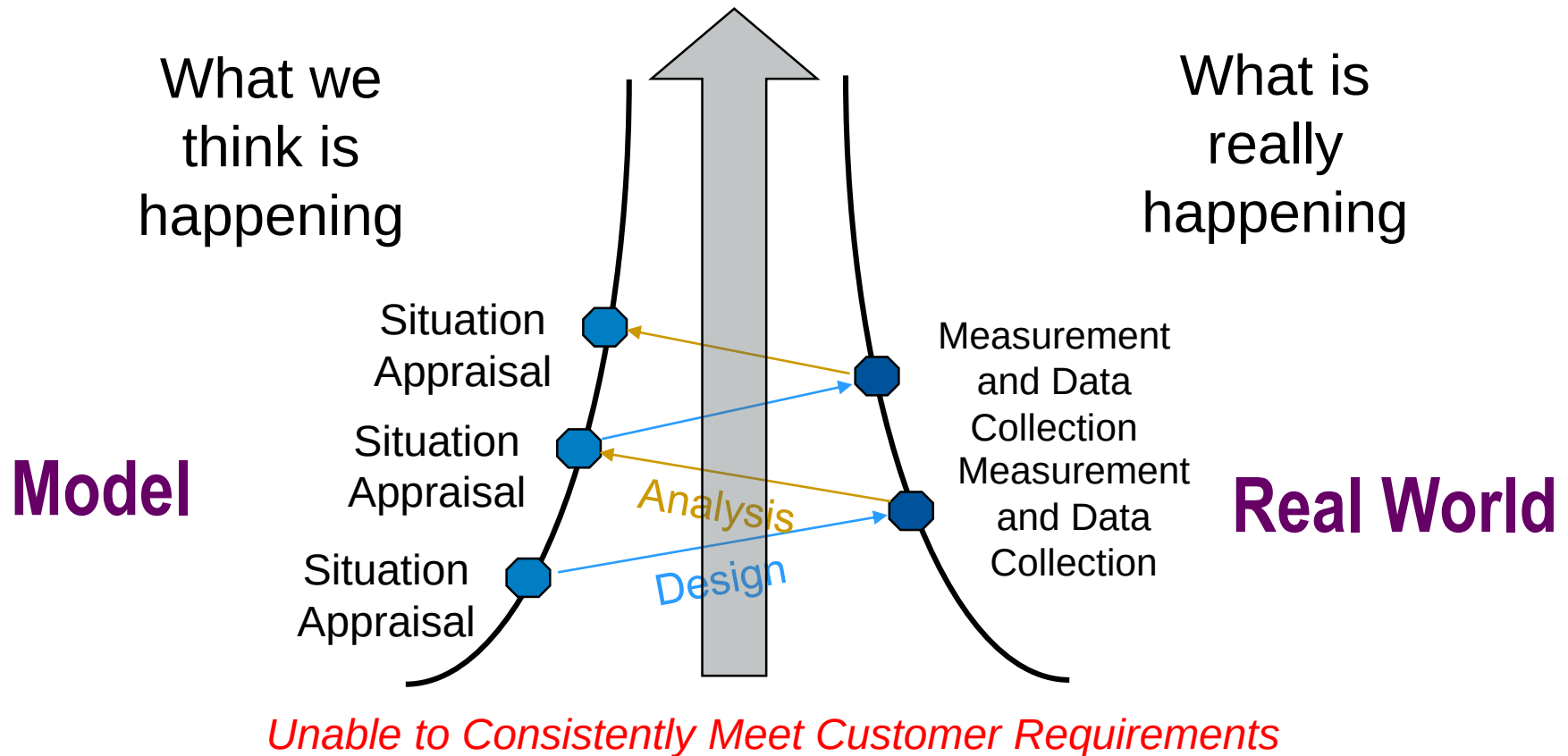


Quality By Design



Why We Need DOE

Able to Consistently Meet Customer Requirements



Methods Before DOE



Ancient Greece - 1600 BC
One Factor At A Time

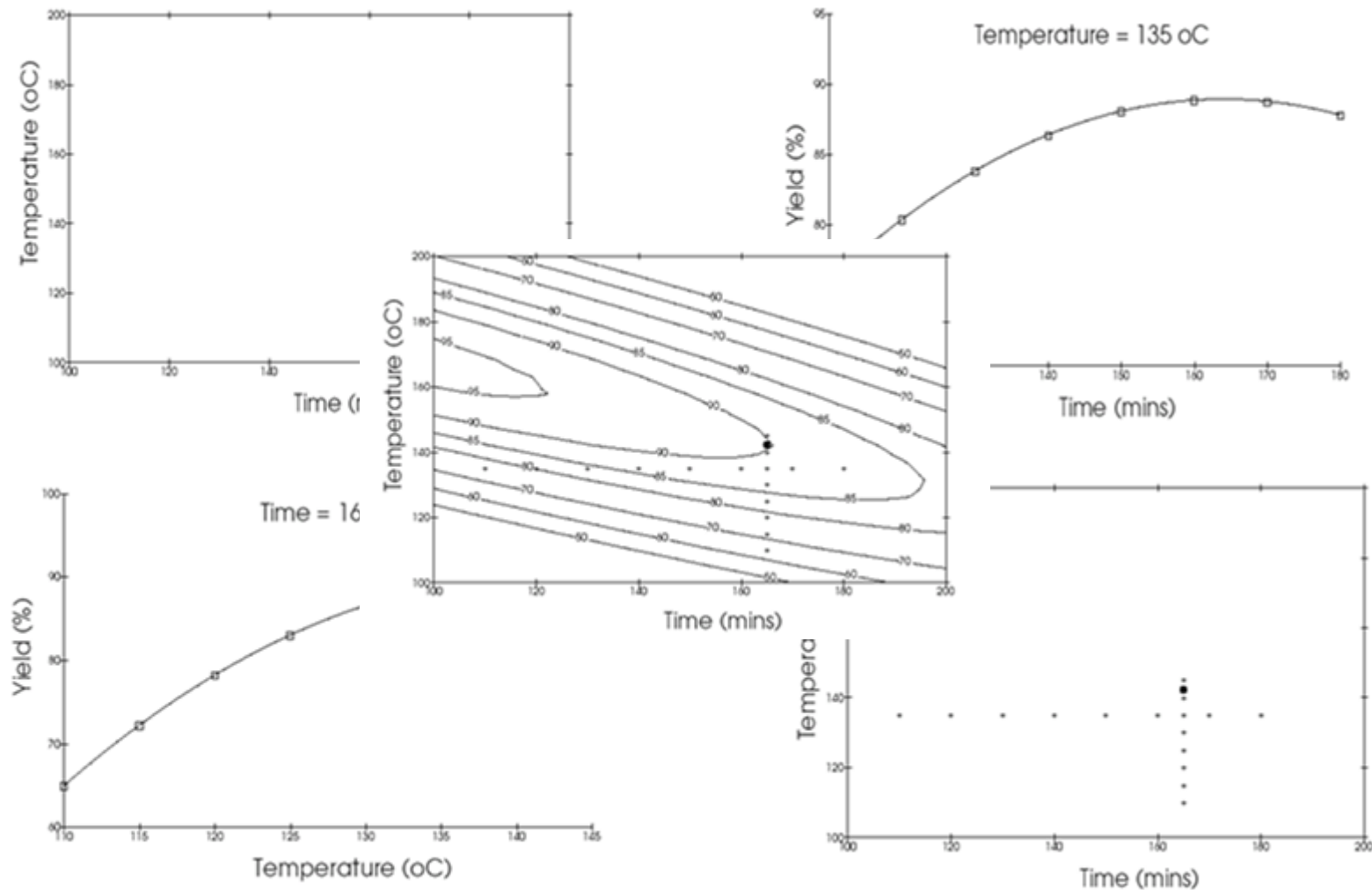


Francis Bacon - 17th Century
Induction



Thomas Edison – 1926
Trial And Error

Shortcoming of The Methods



DOE Giants



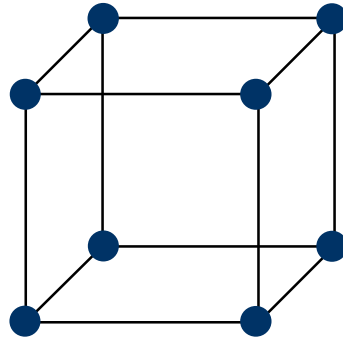
Ronald Aylmer Fisher – (1890~1962)



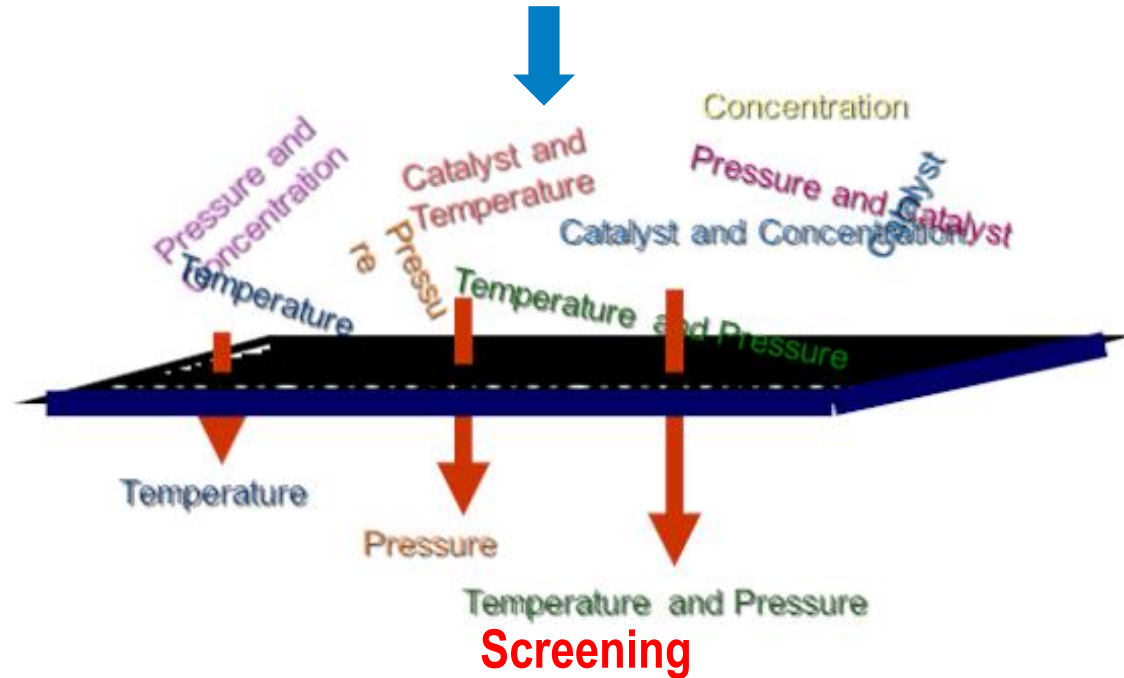
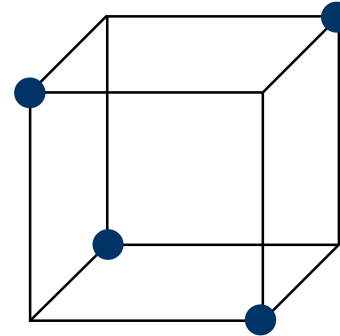
George Edward Pelham Box (1919~2013)

Full Factorial Design

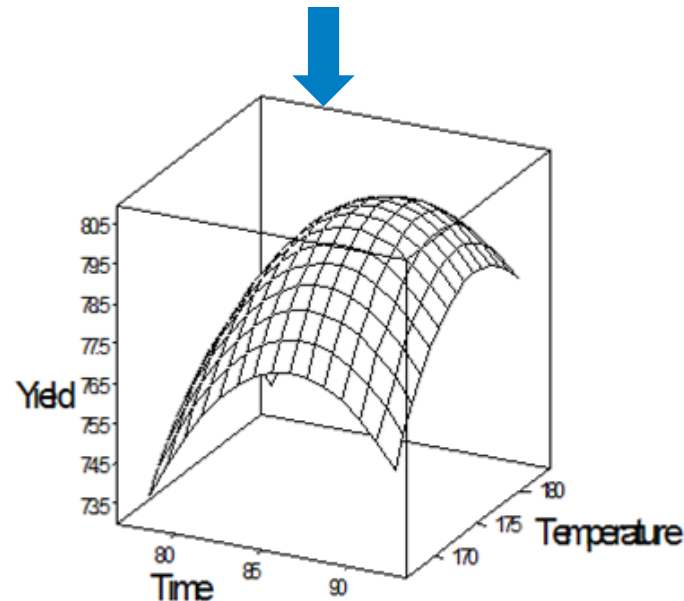
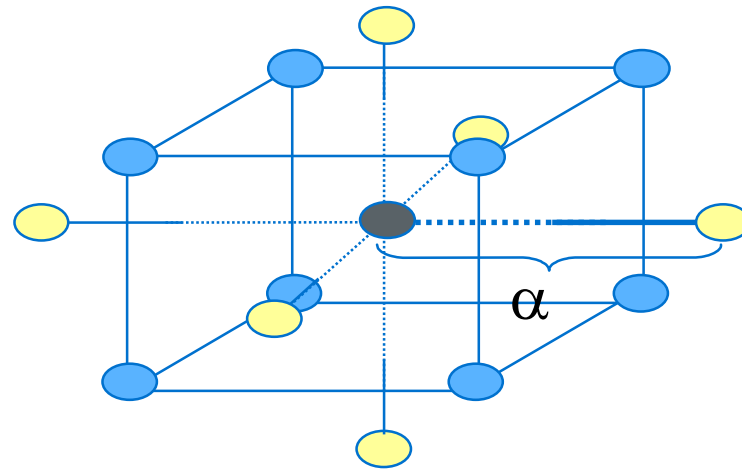
2^3 Full Factorial



Half Fraction 2^3 Full Factorial



Response Surface Design



Optimization

Who Are The Next DOE Pioneers?



Bradley Jones



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Brumbaugh Award Winners

2012	Bradley Jones
2012	Christopher Nachtsheim
2010	George Box and Surendar Narasimhan
2009	Bradley Jones
2009	Christopher J. Nachtsheim
2008	Soren Bisgaard
2007	George E.P. Box
2007	Carmen Paniagua-Quiriones
2006	William H. Woodall

Definitive Screening Design

Foldover pair	Run (i)	Factor levels				
		$x_{i,1}$	$x_{i,2}$	$x_{i,3}$	$\dots$	$x_{i,m}$
1	1	0	± 1	± 1	$\dots$	± 1
	2	0	∓ 1	∓ 1	$\dots$	∓ 1
2	3	± 1	0	± 1	$\dots$	± 1
	4	∓ 1	0	∓ 1	$\dots$	∓ 1
3	5	± 1	± 1	0	$\dots$	± 1
	6	∓ 1	∓ 1	0	$\dots$	∓ 1
$\vdots$	$\vdots$	$\vdots$	$\vdots$	$\vdots$	$\ddots$	$\vdots$
m	$2m - 1$	± 1	± 1	± 1	$\dots$	0
	$2m$	∓ 1	∓ 1	∓ 1	$\dots$	0
Centerpoint	$2m + 1$	0	0	0	$\dots$	0

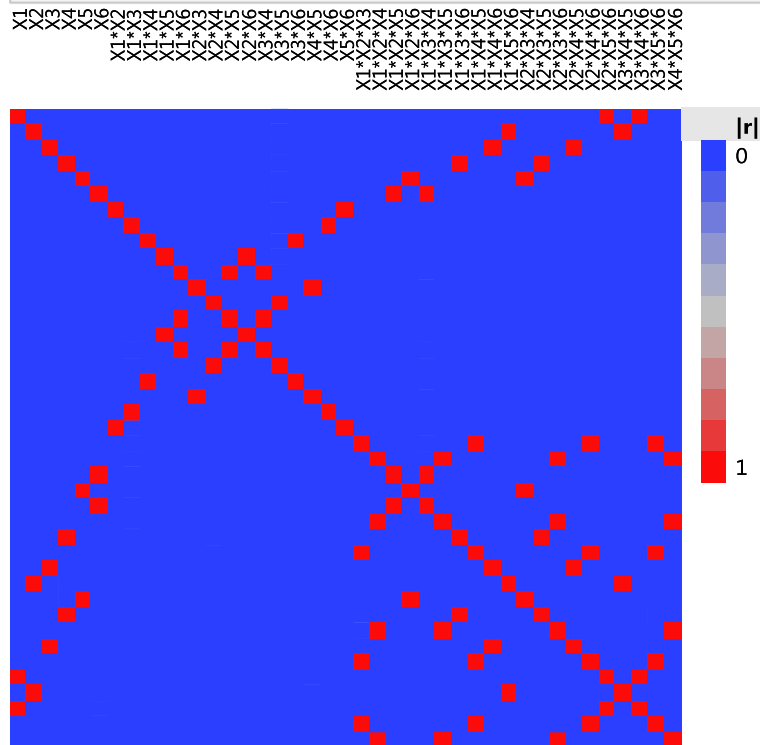
Benefits of DSD

- Discover key 1st and 2nd order effects in fewer runs.
- Avoid aliasing of 2nd order effects by reducing the need for subsequent runs.
- Increase DOE efficiency with the integration of screening and optimization in one round of experiments.

Comparison of DOE

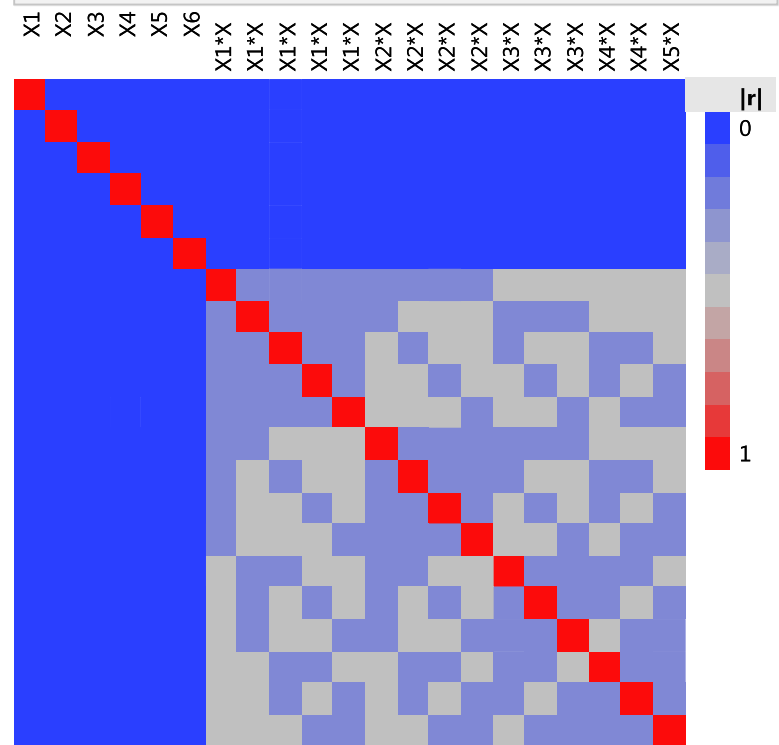
- Classical Screening Design
 - 6 continuous factors
 - 16 runs
 - Resolution = IV

Color Map On Correlations

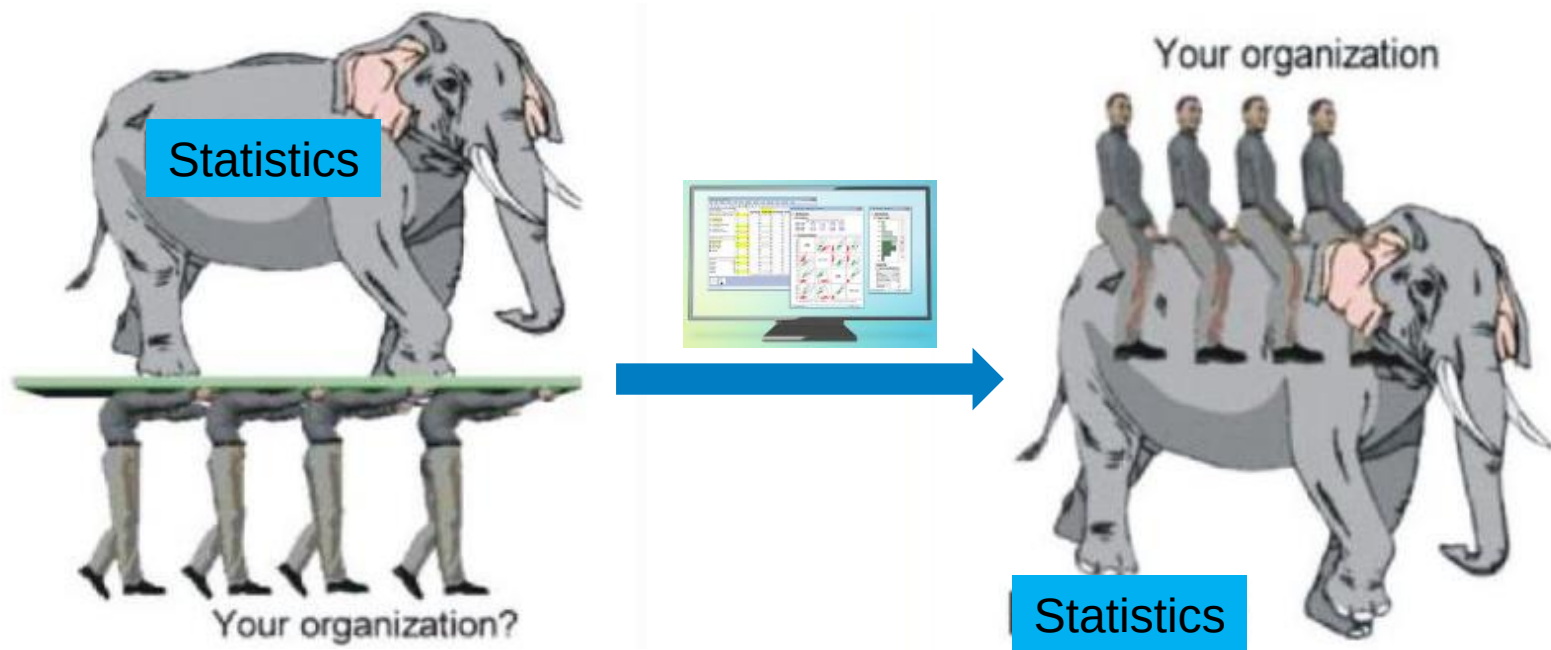


- Definitive Screening Design
 - 6 continuous factors
 - 13 runs
 - Resolution > IV

Color Map On Correlations



Don't Worry The World of Statistics





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敏捷分析，成就无限



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