Quality-by-Design

Taguchi Quality Engineering

Carl Perini
Ashland Specialty Ingredients - Corporate Quality
ASQ North Jersey - Education Committee
19-October-2011

Genichi Taguchi (1924 -)

Quality Concept & Loss function

Process types:

- bigger-the-better
- smaller-the-better
- nominal-the-best

Genichi Taguchi

Definition of Quality:
On-Target with Minimum Variation = Process Goal

Conformance to requirements is incomplete

Process target is minimum cost - Loss function

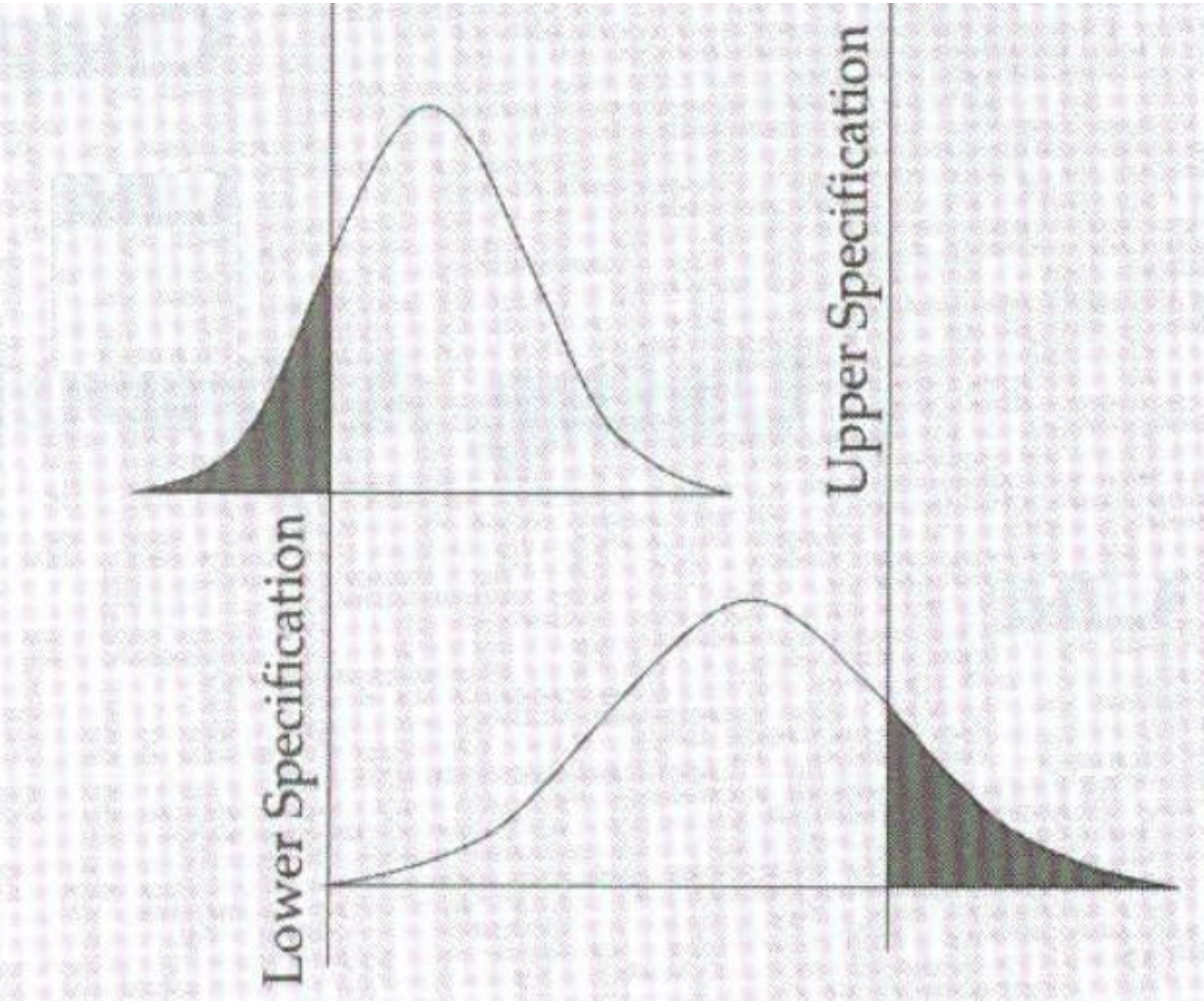
Genichi Taguchi

Conformance to Requirements weaknesses
Commercial Objectives/Product Specifications

Set by Whom?
How are they set?
Where do they come from?

Close line between
FAIL | PASS | FAIL

Genichi Taguchi – On-Target?



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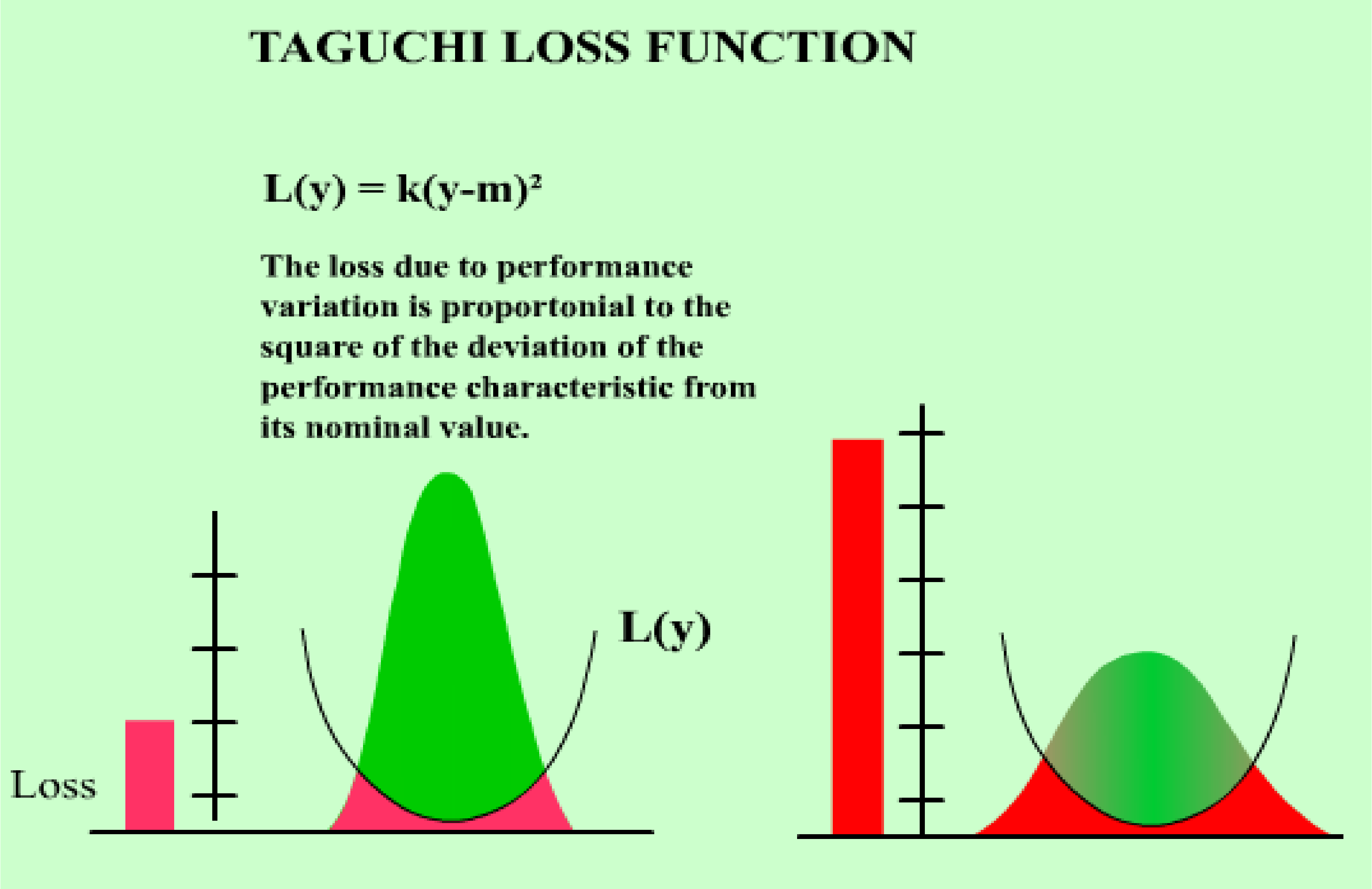
Genichi Taguchi – Minimum Variation?



TAGUCHI LOSS FUNCTION

$$L(y) = k(y-m)^2$$

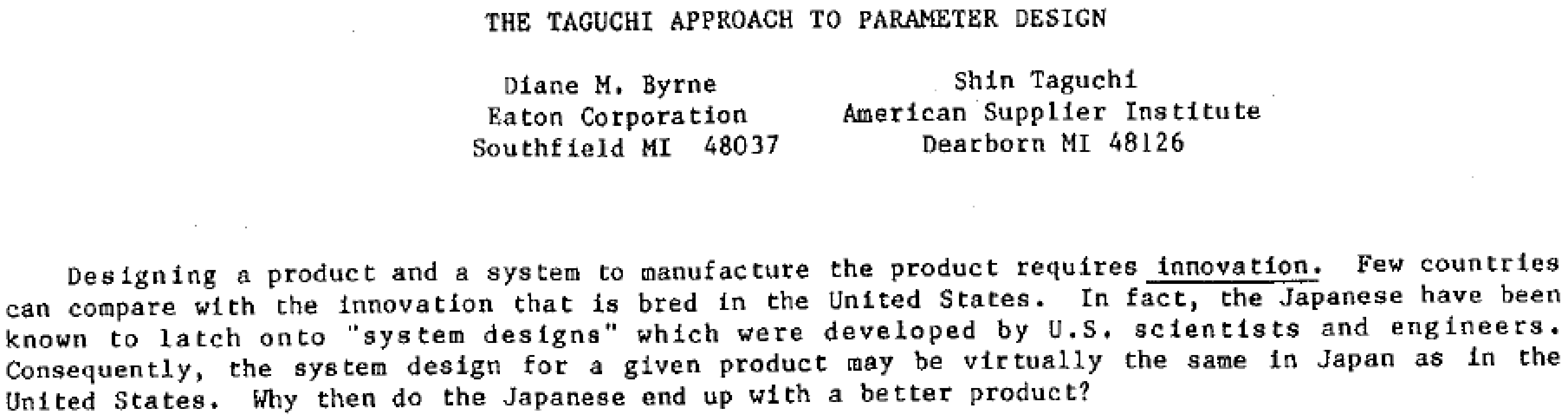
The loss due to performance variation is proportional to the square of the deviation of the performance characteristic from its nominal value.

http://elsmar.com/Taguchi.html

Robust Design Introduction

Dr. Genichi Taguchi wrote that the United States has coined the term “Taguchi Methods” to describe his system of robustness for the evaluation and improvement of the product development processes.

He has stated that he preferred the term “quality engineering” to describe the process.



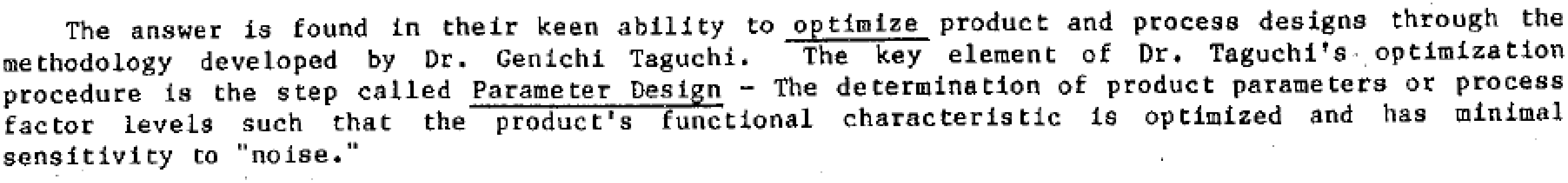
THE TAGUCHI APPROACH TO PARAMETER DESIGN

Diane M. Byrne
Eaton Corporation
Southfield MI 48037

Shin Taguchi
American Supplier Institute
Dearborn MI 48126

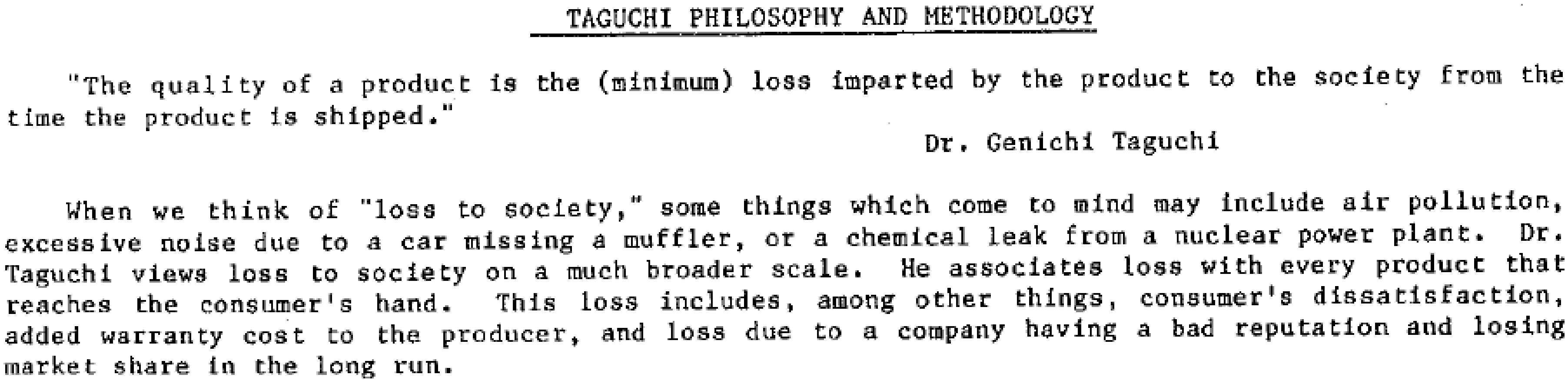
Designing a product and a system to manufacture the product requires innovation. Few countries can compare with the innovation that is bred in the United States. In fact, the Japanese have been known to latch onto "system designs" which were developed by U.S. scientists and engineers. Consequently, the system design for a given product may be virtually the same in Japan as in the United States. Why then do the Japanese end up with a better product?

Byrne & Taguchi



The answer is found in their keen ability to *optimize* product and process designs through the methodology developed by Dr. Genichi Taguchi. The key element of Dr. Taguchi's optimization procedure is the step called *Parameter Design* - The determination of product parameters or process factor levels such that the product's functional characteristic is optimized and has minimal sensitivity to "noise."

Byrne & Taguchi



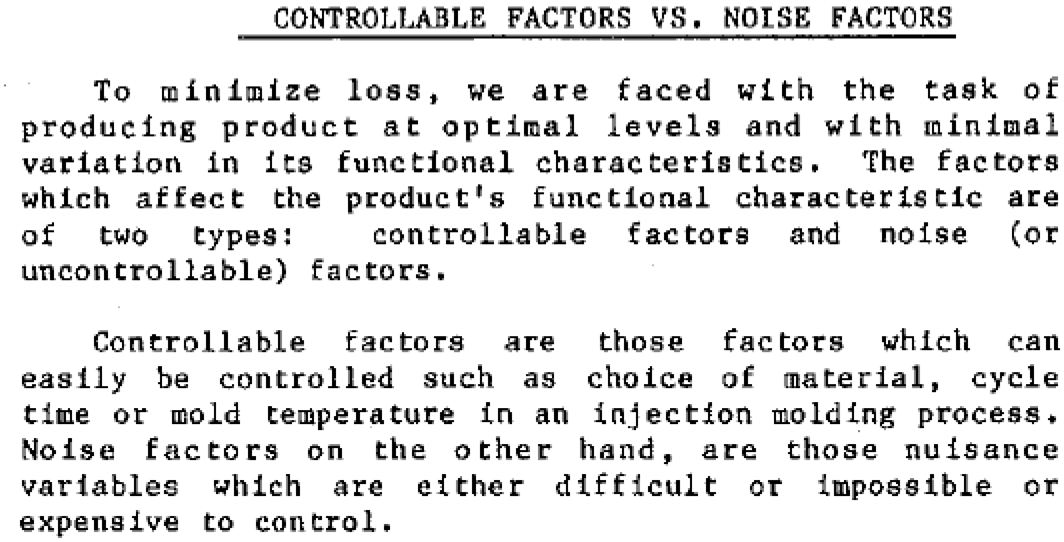
TAGUCHI PHILOSOPHY AND METHODOLOGY

"The quality of a product is the (minimum) loss imparted by the product to the society from the time the product is shipped."

Dr. Genichi Taguchi

When we think of "loss to society," some things which come to mind may include air pollution, excessive noise due to a car missing a muffler, or a chemical leak from a nuclear power plant. Dr. Taguchi views loss to society on a much broader scale. He associates loss with every product that reaches the consumer's hand. This loss includes, among other things, consumer's dissatisfaction, added warranty cost to the producer, and loss due to a company having a bad reputation and losing market share in the long run.

Byrne & Taguchi

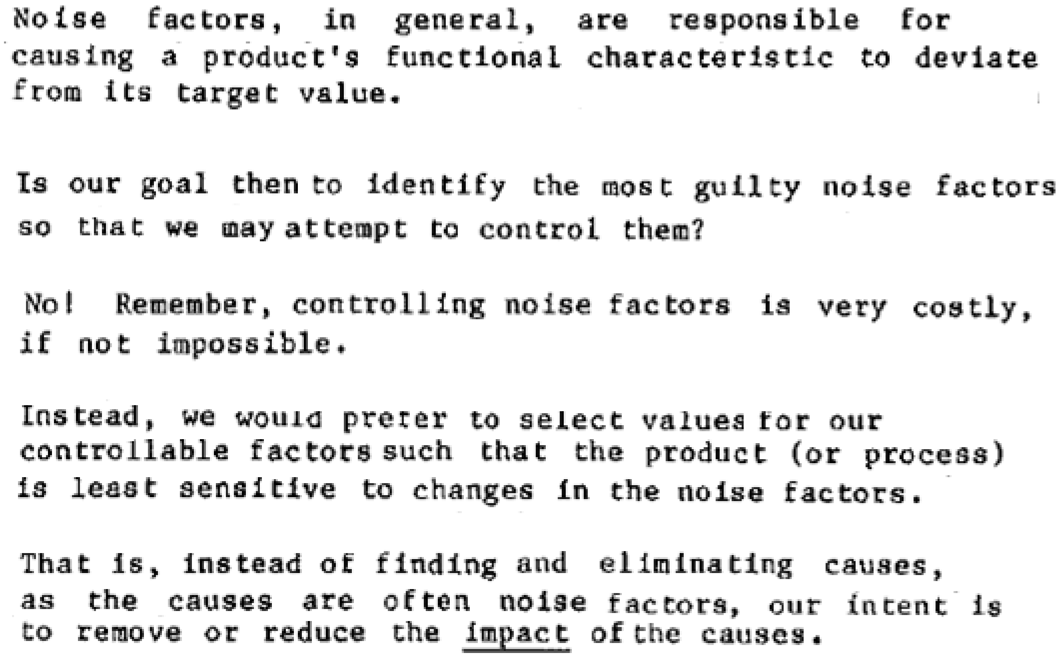


CONTROLLABLE FACTORS VS. NOISE FACTORS

To minimize loss, we are faced with the task of producing product at optimal levels and with minimal variation in its functional characteristics. The factors which affect the product's functional characteristic are of two types: controllable factors and noise (or uncontrollable) factors.

Controllable factors are those factors which can easily be controlled such as choice of material, cycle time or mold temperature in an injection molding process. Noise factors on the other hand, are those nuisance variables which are either difficult or impossible or expensive to control.

Byrne & Taguchi



Noise factors, in general, are responsible for causing a product's functional characteristic to deviate from its target value.

Is our goal then to identify the most guilty noise factors so that we may attempt to control them?

No! Remember, controlling noise factors is very costly, if not impossible.

Instead, we would prefer to select values for our controllable factors such that the product (or process) is least sensitive to changes in the noise factors.

That is, instead of finding and eliminating causes, as the causes are often noise factors, our intent is to remove or reduce the <u>impact</u> of the causes.

Byrne & Taguchi

Robust Design Approach

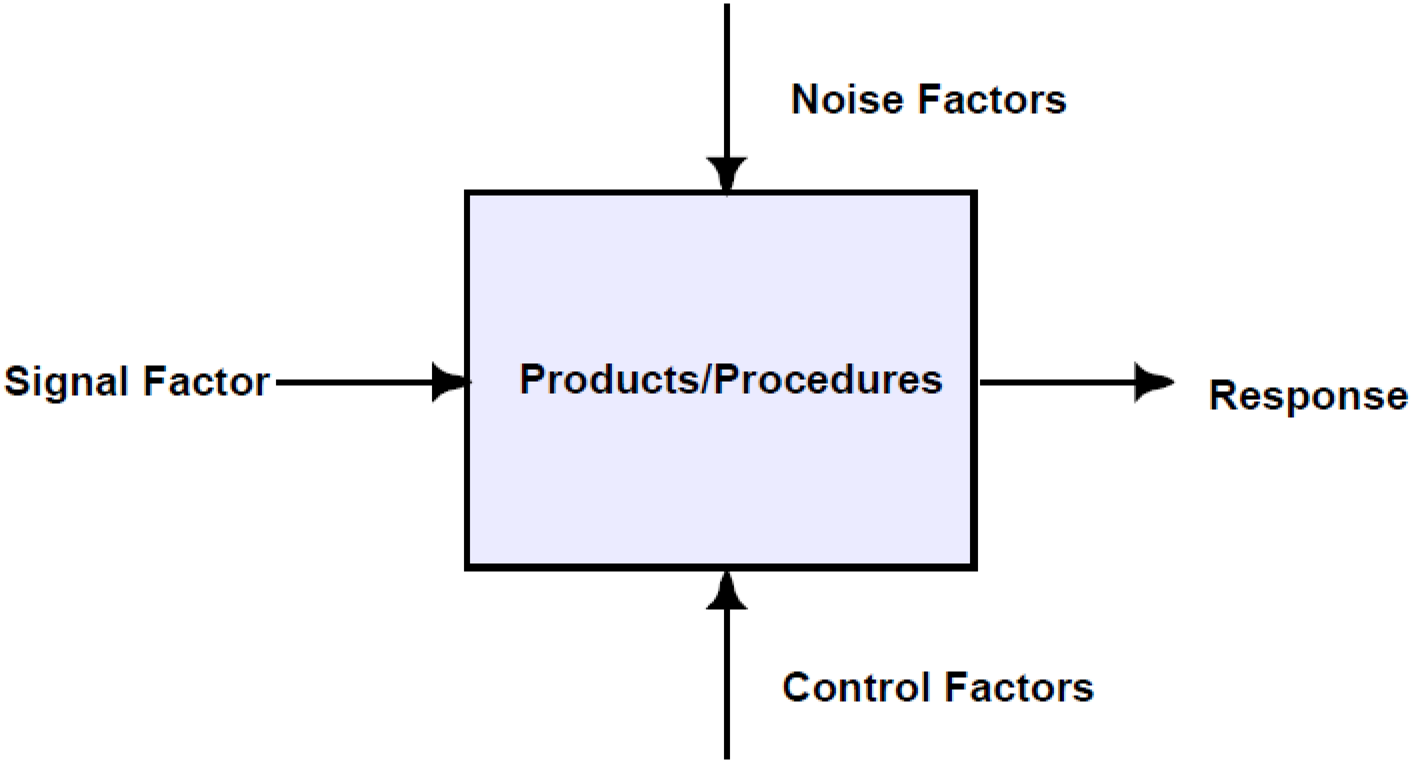
Robust design processes can produce extremely reliable designs both during manufacture and in use.

Robust design uses the concept of parameter control to place the design in a position where random “noise” does not cause failure.

The concept is that a product or process is controlled by a number of factors to produce the desired response.

Robust Design Approach

The signal factor is the signal used for the intended response. The success of obtaining the response is dependent on control factors and noise factors.



Noise Factors

Signal Factor

Products/Procedures

Response

Control Factors

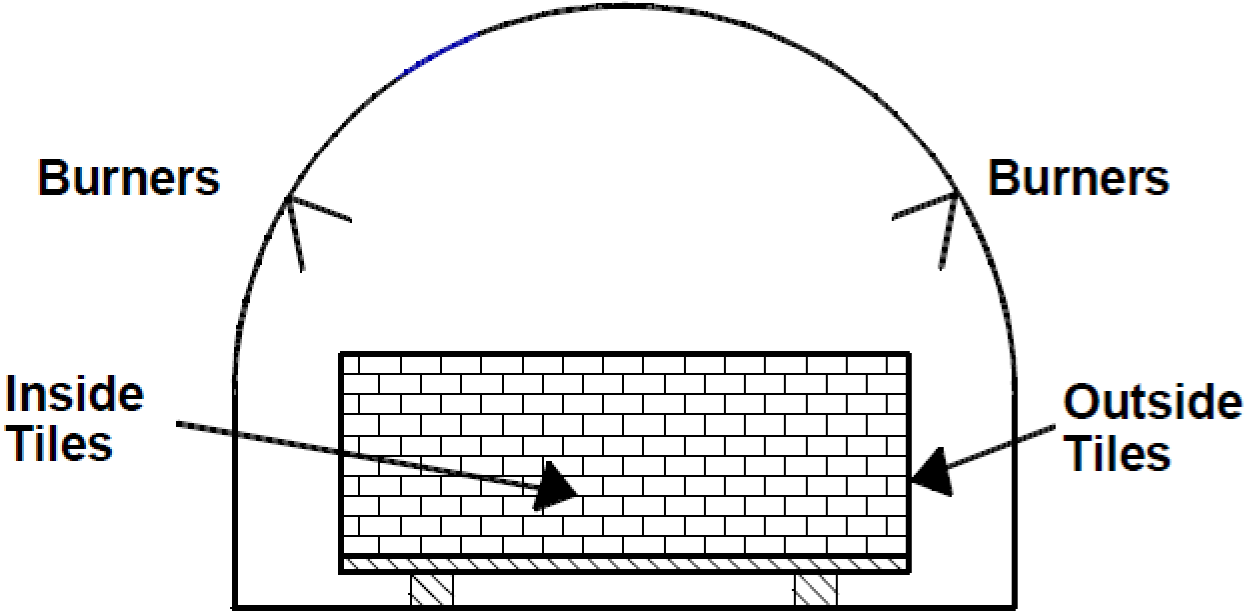
Robust Design Example

The most celebrated case of design of experiments was that of a parameter design experiment at a tile manufacturing company in Japan, as documented by Genichi Taguchi.

Factors which were less expensive to control were fixed at levels such that the variation in tile dimension was made insensitive to a noise factor, temperature variation.

Robust Design Example

The problem was extreme variation in the dimensions of the tile produced. Tiles in the kiln toward the outside of the stack tended to have a different average dimension and exhibited more variation than those toward the inside of the stack.



Robust Design Example

The cause of variation was an uneven temperature profile inside the kiln. The company would have to redesign the kiln, which was very expensive. The company budget didn't allow such costly action, but the kiln was creating a tremendous financial loss.

Although temperature was an important factor, it was treated as a noise factor. People having knowledge about the process brainstormed and identified seven major controllable factors which they thought could affect the tile dimension. These were: (1) limestone content in the raw mix, (2) fineness of the additives, (3) amalgamate content, (4) type of amalgamate, (5) raw material quantity, (6) waste return content, and (7) type of feldspar.

Robust Design Example

After testing these factors using an orthogonal design, they discovered that factor #1 (limestone content) was the most significant factor, although other factors had smaller effects. By increasing limestone content from 1% to 2%, the percent warpage could be reduced from 30% to less than 1%. Limestone was the cheapest material in the tile mix. They found that they could use a smaller amount of amalgamate without adversely affecting the tile dimension. Amalgamate was the most expensive material in the tile.

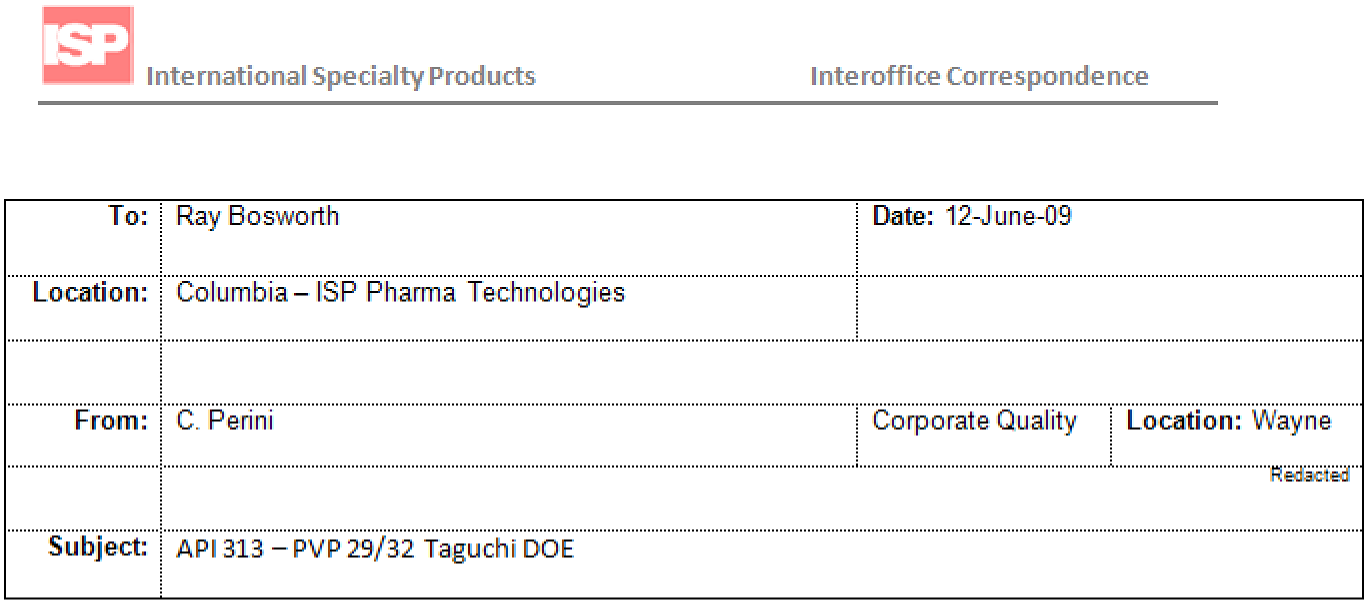
Functional Requirements

In the development of a new product, the product planning department must determine the functions required. The designer will have a set of requirements that a new product must possess. The designer will develop various concepts, embodiments, or systems that will satisfy the customer's requirements.

The product design must be "functionally robust," which implies that it must withstand variation in input conditions and still achieve desired performance capabilities. The designer has two objectives:

- Develop a product that can perform the desired functions and be robust under various operating or exposure conditions

- Have the product manufactured at the lowest possible cost



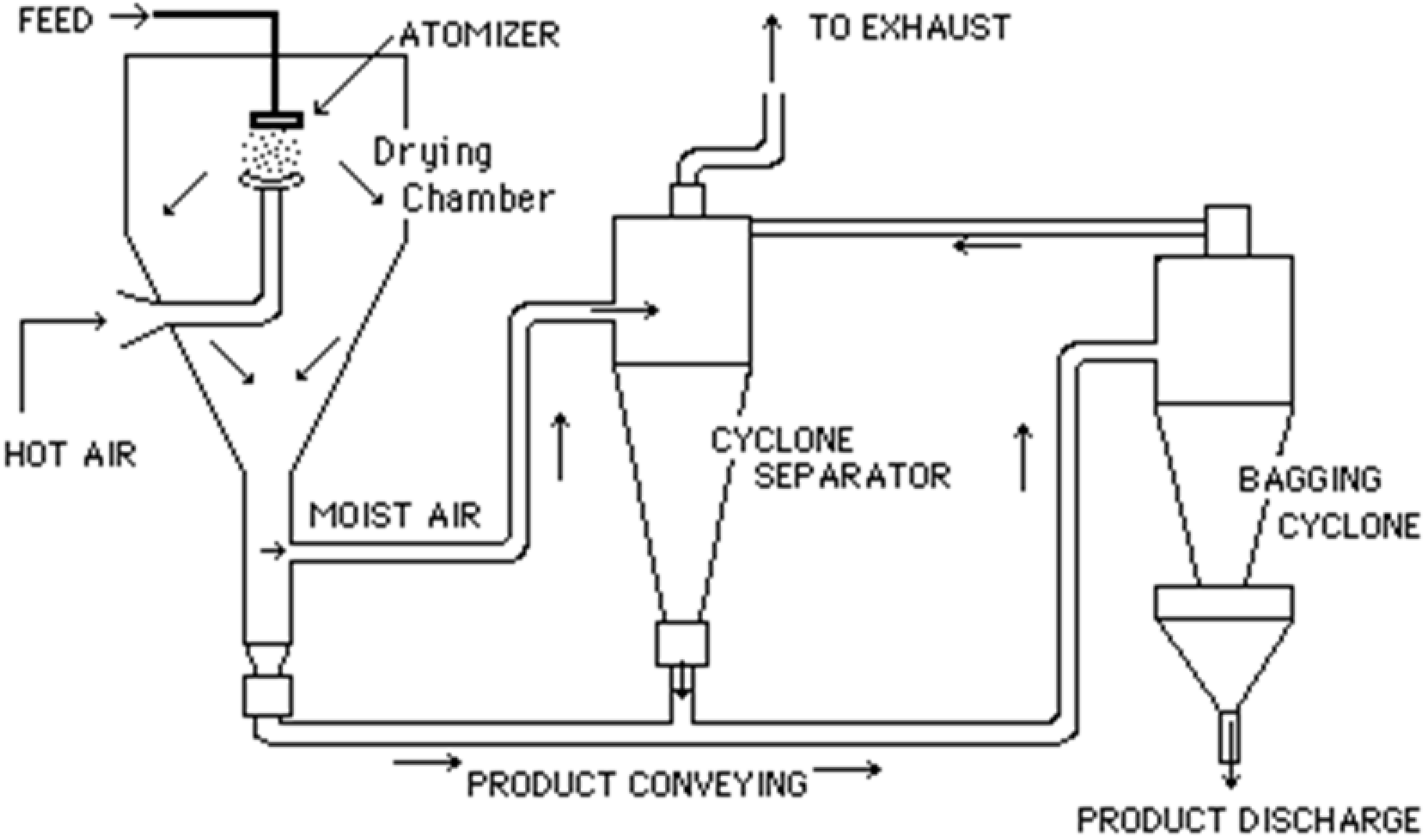
International Specialty Products Interoffice Correspondence

To:	Ray Bosworth	**Date:** 12-June-09	
Location:	Columbia – ISP Pharma Technologies		
From:	C. Perini	Corporate Quality	**Location:** Wayne
			Redacted
Subject:	API 313 – PVP 29/32 Taguchi DOE		

ISP case study

Spray Drying Equipment

Spray Drying Equipment



SUMMARY

In summary, the Taguchi method involves the following steps:

1. Determine the appropriate response variable(s) for the product design or process to be studied. OBJECTIVE - WHAT TO MEASURE

2. Identify design (controllable) factors and noise (uncontrollable) factors which could affect the response. Determine appropriate levels over which the factors should be tested. BRAINSTORM FIRST FOR ALL FACTORS, THEN CLASSIFY THEM INTO CONTROLLABLE VS. NOISE.

3. Identify potential interactions, if any.

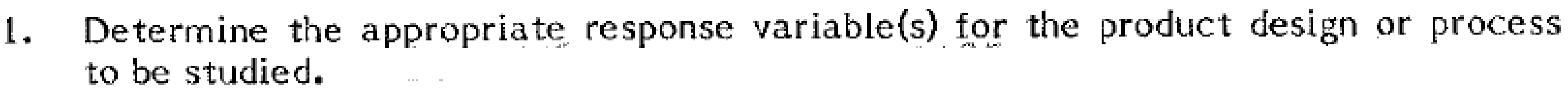
4. Construct the experimental design by choosing appropriate orthogonal arrays for the design factors and the noise factors.

5. Carefully plan the test conduct (and estimate cost of running the experiment), then carry out the parameter design experiment. MATERIALS, TIME, LABOR
INCLUDE ALL TESTS, CONFIRMATION TESTS.

6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.

7. Run a confirmation experiment to confirm that the new settings do indeed improve the S/N ratio.

8. Perform a tolerance design if needed.



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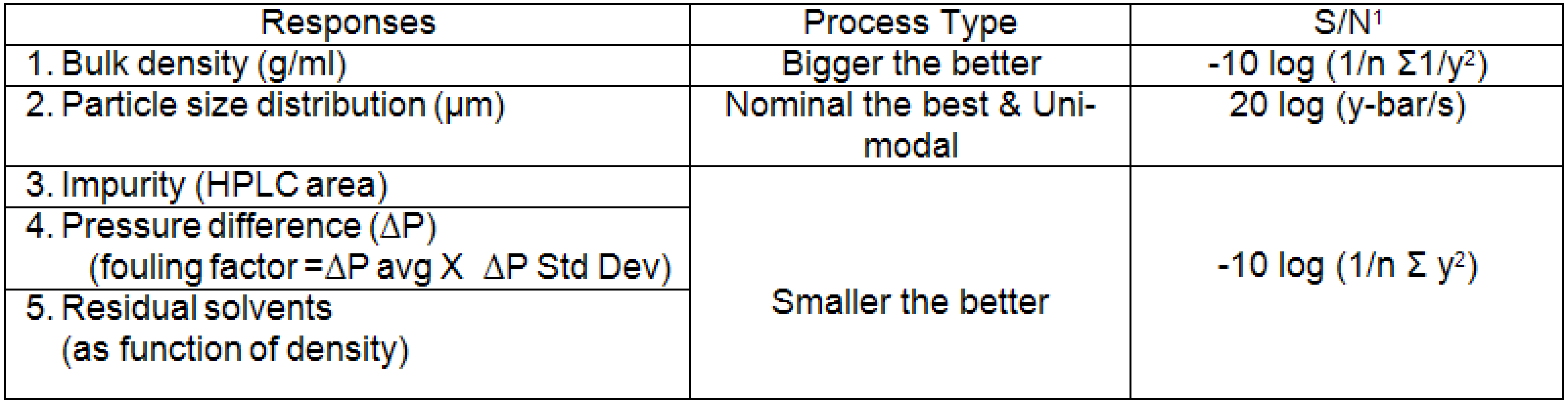
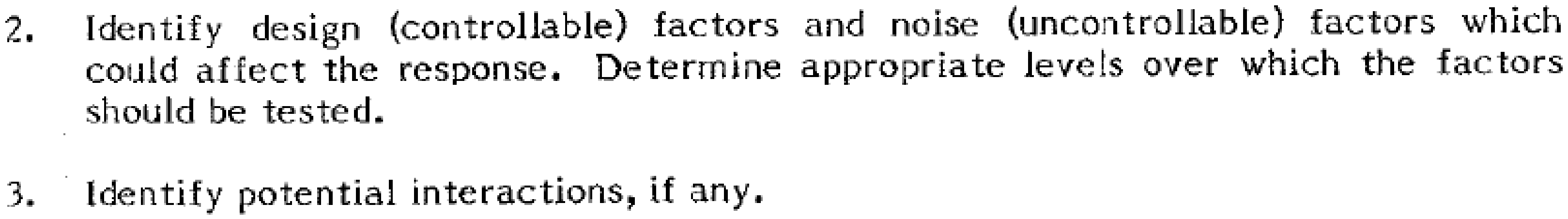


Responses	Process Type	S/N[1]
1. Bulk density (g/ml)	Bigger the better	$-10 \log (1/n\ \Sigma 1/y^2)$
2. Particle size distribution (µm)	Nominal the best & Uni-modal	$20 \log (\bar{y}/s)$
3. Impurity (HPLC area)	Smaller the better	$-10 \log (1/n\ \Sigma\ y^2)$
4. Pressure difference (ΔP) (fouling factor =ΔP avg X ΔP Std Dev)		
5. Residual solvents (as function of density)		

ISP case study



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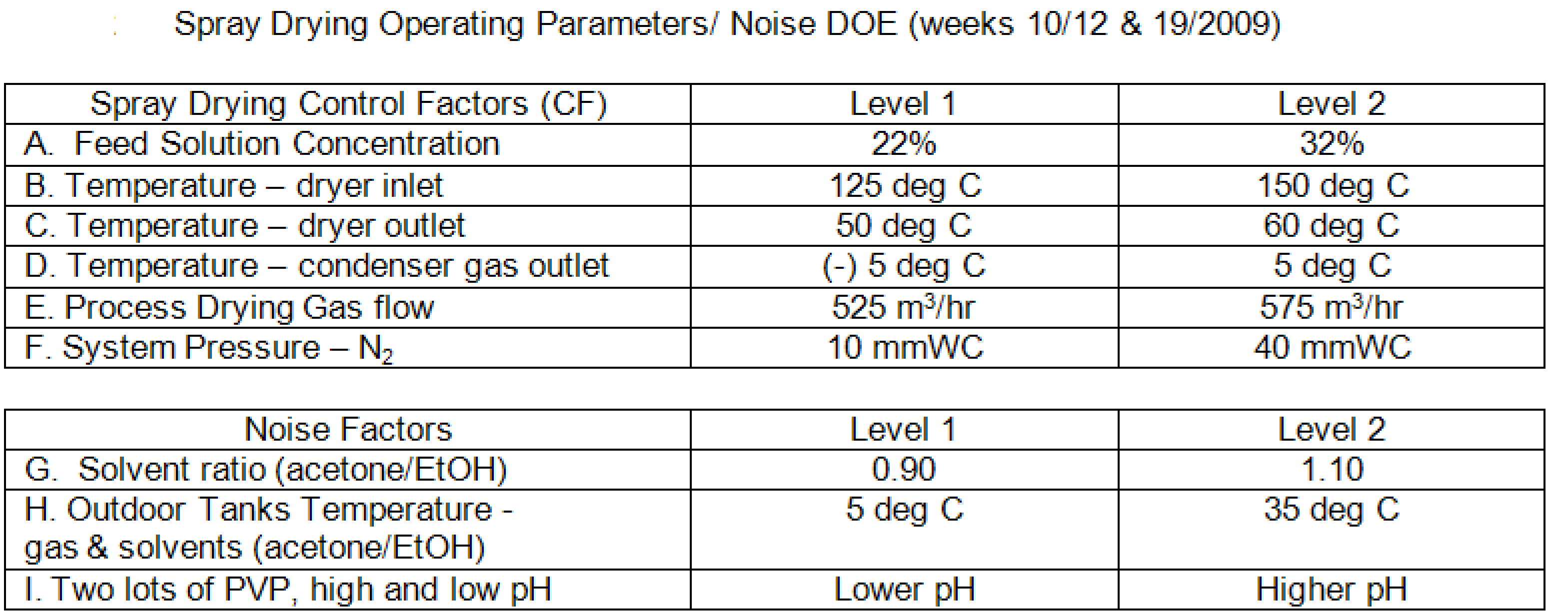


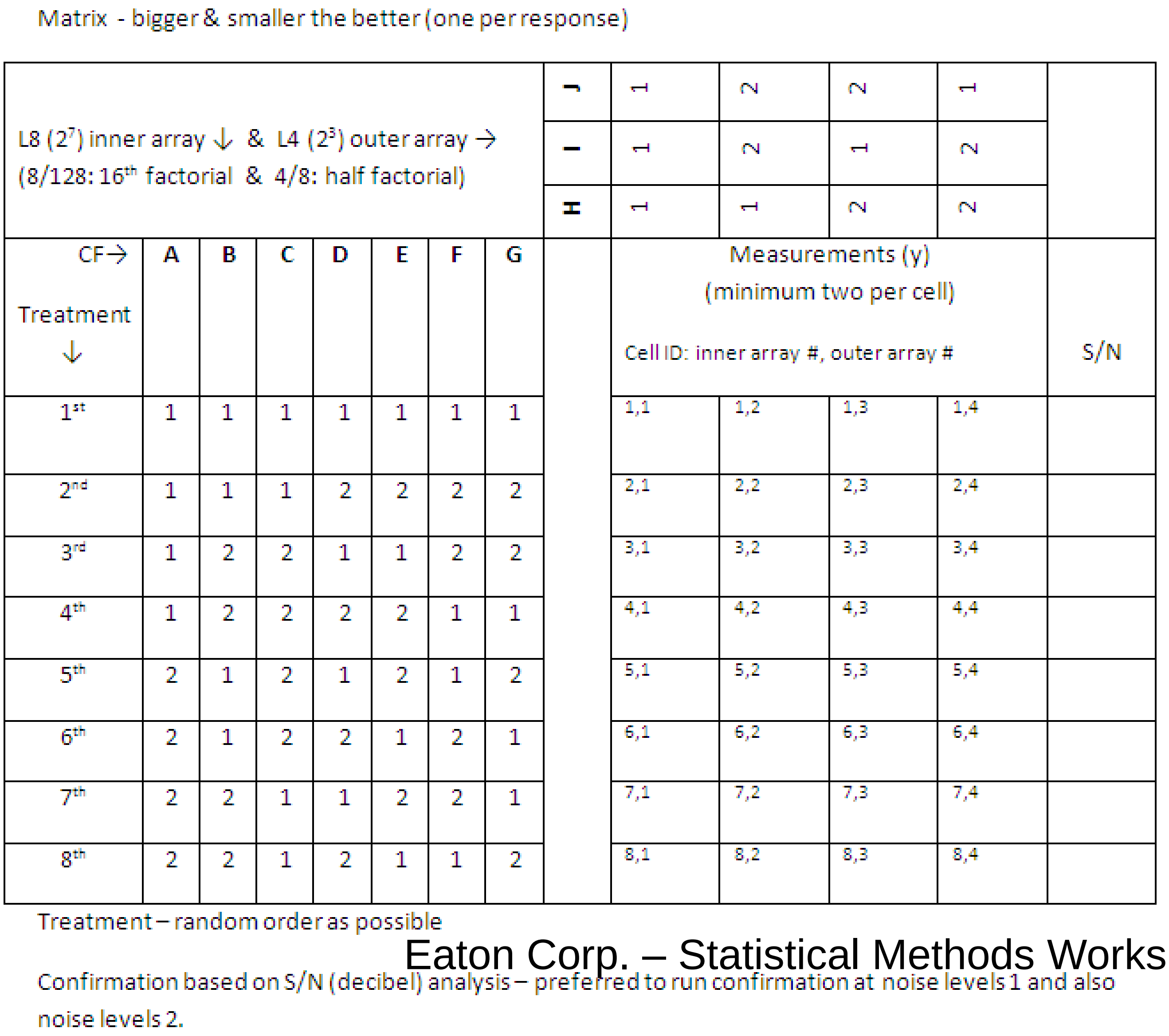
Spray Drying Operating Parameters/ Noise DOE (weeks 10/12 & 19/2009)

Spray Drying Control Factors (CF)	Level 1	Level 2
A. Feed Solution Concentration	22%	32%
B. Temperature – dryer inlet	125 deg C	150 deg C
C. Temperature – dryer outlet	50 deg C	60 deg C
D. Temperature – condenser gas outlet	(-) 5 deg C	5 deg C
E. Process Drying Gas flow	525 m^3/hr	575 m^3/hr
F. System Pressure – N_2	10 mmWC	40 mmWC

Noise Factors	Level 1	Level 2
G. Solvent ratio (acetone/EtOH)	0.90	1.10
H. Outdoor Tanks Temperature - gas & solvents (acetone/EtOH)	5 deg C	35 deg C
I. Two lots of PVP, high and low pH	Lower pH	Higher pH

ISP case study

4. Construct the experimental design by choosing appropriate orthogonal arrays for the design factors and the noise factors.

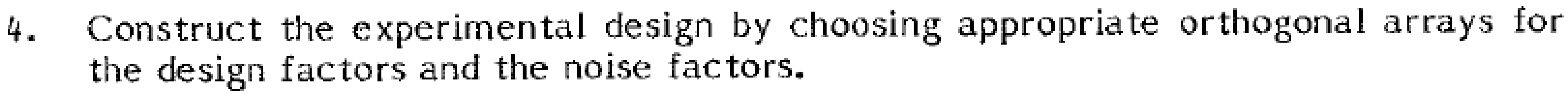


Matrix - bigger & smaller the better (one per response)

L8 (2^7) inner array ↓ & L4 (2^3) outer array → (8/128: 16th factorial & 4/8: half factorial)								J	1	2	2	1	
								I	1	2	1	2	
								H	1	1	2	2	
CF→ Treatment ↓	A	B	C	D	E	F	G		Measurements (y) (minimum two per cell) Cell ID: inner array #, outer array #				S/N
1st	1	1	1	1	1	1	1		1,1	1,2	1,3	1,4	
2nd	1	1	1	2	2	2	2		2,1	2,2	2,3	2,4	
3rd	1	2	2	1	1	2	2		3,1	3,2	3,3	3,4	
4th	1	2	2	2	2	1	1		4,1	4,2	4,3	4,4	
5th	2	1	2	1	2	1	2		5,1	5,2	5,3	5,4	
6th	2	1	2	2	1	2	1		6,1	6,2	6,3	6,4	
7th	2	2	1	1	2	2	1		7,1	7,2	7,3	7,4	
8th	2	2	1	2	1	1	2		8,1	8,2	8,3	8,4	

Treatment – random order as possible

Confirmation based on S/N (decibel) analysis – preferred to run confirmation at noise levels 1 and also noise levels 2.



4. Construct the experimental design by choosing appropriate orthogonal arrays for the design factors and the noise factors.

Classical experiments focus on 1FAT (one factor at a time) at two or three levels and attempt to hold everything else constant. DOE can focus on a wide range of key input factors or variables and will determine the optimum levels of each of the factors. The Pareto principle applies to the world of experimentation. 20% of the input factors generally make 80% of the impact on the result.

The classical approach to experimentation, changing just one factor at a time, has shortcomings:

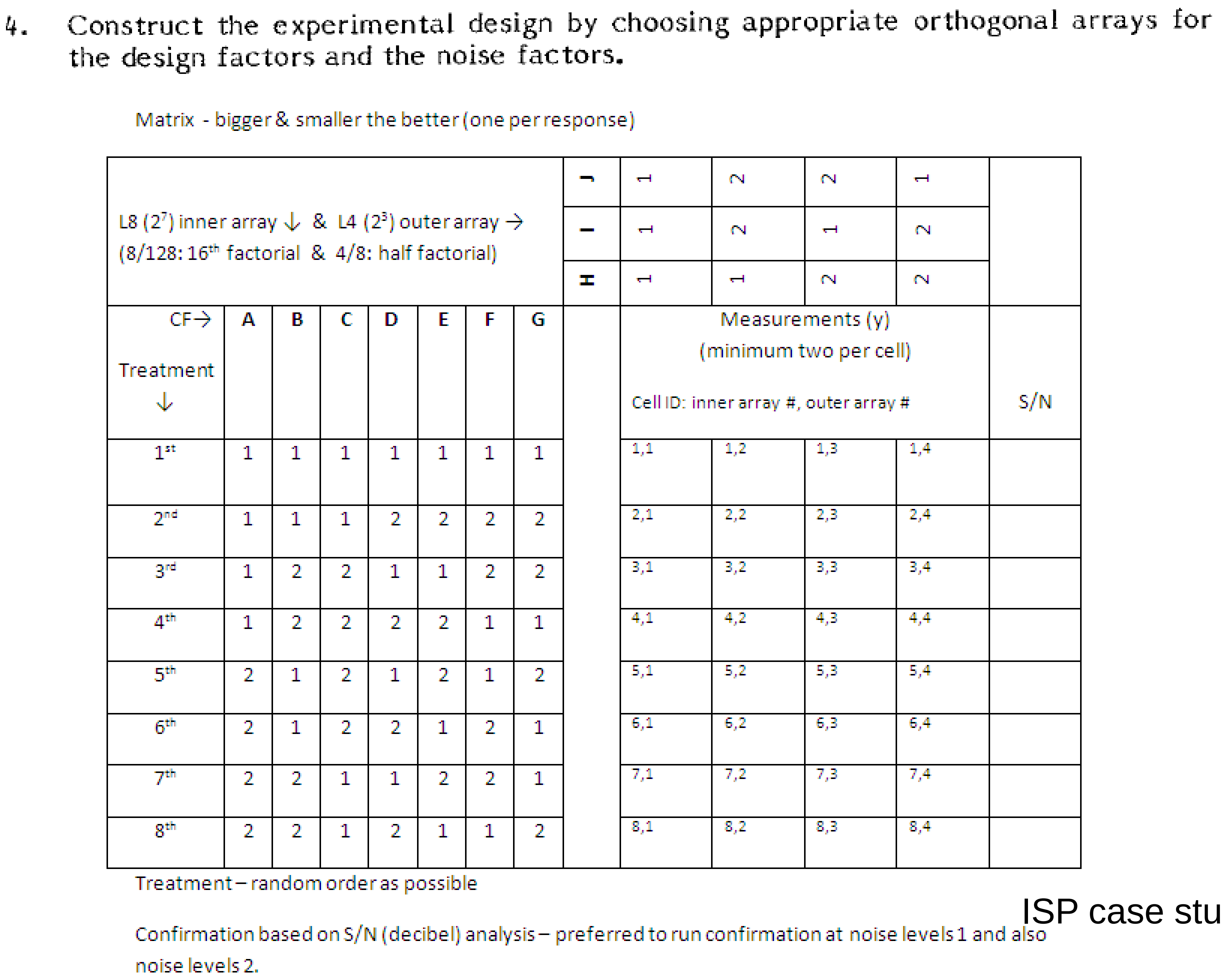
- Too many experiments are necessary.
- The optimum combination of all the variables may never be revealed.
- The interaction between factors cannot be determined.
- Conclusions may be wrong or misleading.
- Many of the observed effects tend to be mysterious.
- Time and effort may be wasted by studying the wrong variables or obtaining improper data.

Design of experiments overcomes these problems by careful planning. Advantages of DOE include:

- Many factors can be evaluated simultaneously, making the DOE process economical.
- Input factors can be controlled to make the output insensitive to noise factors.
- In-depth, statistical knowledge is not always necessary to get big benefit.
- One can look at a process with few experiments.

Advantages of DOE include:

- **Since the designs are balanced, there is confidence in the conclusions.**
- **If important factors are overlooked in an experiment, the results will indicate that fact.**
- **Precise statistical analysis can be run using standard computer programs.**
- **Results can be improved with low costs.**



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Matrix - bigger & smaller the better (one per response)

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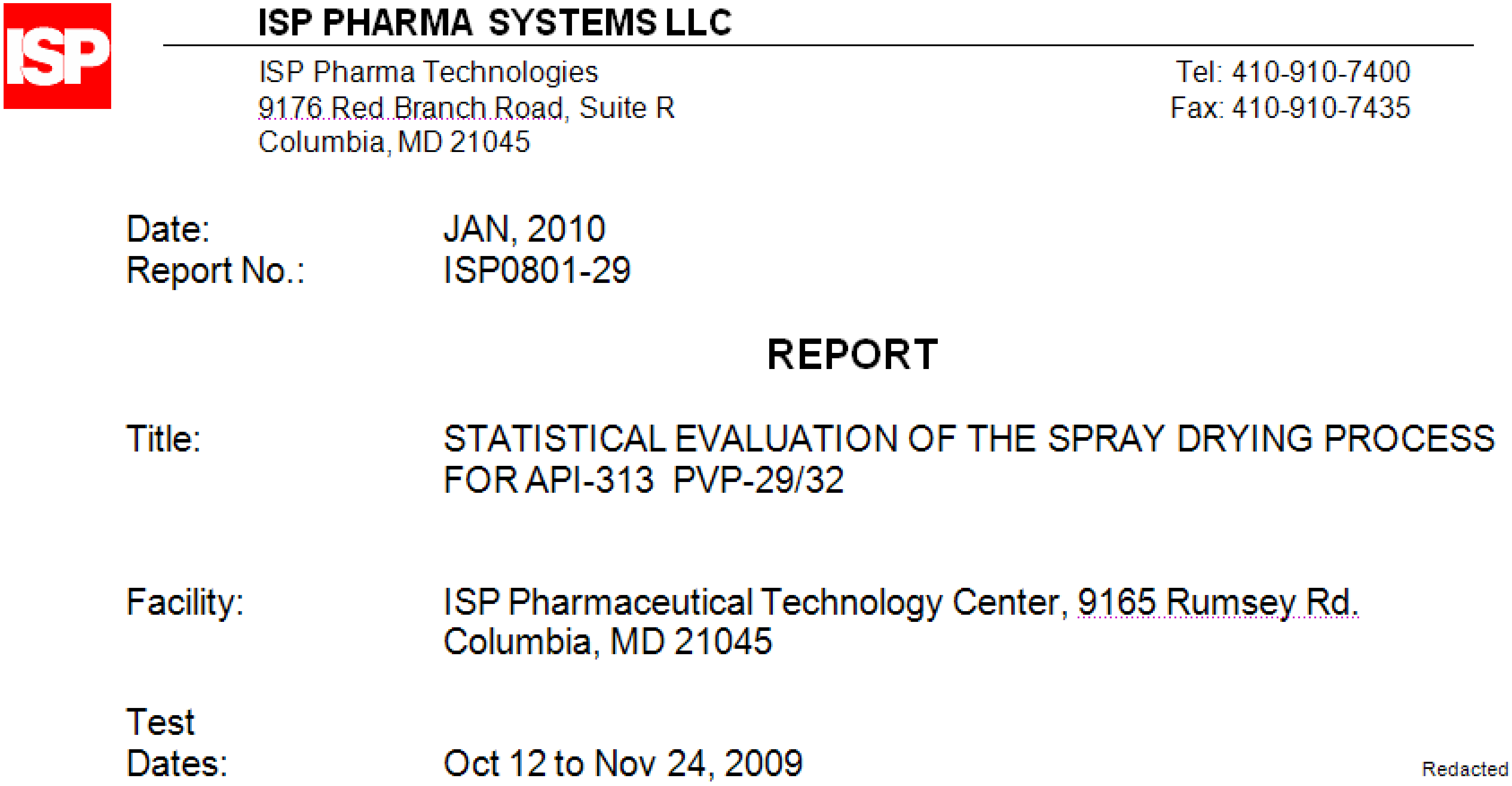
CF→ Treatment ↓	A	B	C	D	E	F	G		Measurements (y) (minimum two per cell) Cell ID: inner array #, outer array #			S/N
1st	1	1	1	1	1	1	1		1,1	1,2	1,3	1,4	
2nd	1	1	1	2	2	2	2		2,1	2,2	2,3	2,4	
3rd	1	2	2	1	1	2	2		3,1	3,2	3,3	3,4	
4th	1	2	2	2	2	1	1		4,1	4,2	4,3	4,4	
5th	2	1	2	1	2	1	2		5,1	5,2	5,3	5,4	
6th	2	1	2	2	1	2	1		6,1	6,2	6,3	6,4	
7th	2	2	1	1	2	2	1		7,1	7,2	7,3	7,4	
8th	2	2	1	2	1	1	2		8,1	8,2	8,3	8,4	

Treatment – random order as possible

Confirmation based on S/N (decibel) analysis – preferred to run confirmation at noise levels 1 and also noise levels 2.

ISP case study

5. Carefully plan the test conduct (and estimate cost of running the experiment), then carry out the parameter design experiment.



ISP PHARMA SYSTEMS LLC

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Columbia, MD 21045

Tel: 410-910-7400
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Date: JAN, 2010
Report No.: ISP0801-29

REPORT

Title: STATISTICAL EVALUATION OF THE SPRAY DRYING PROCESS FOR API-313 PVP-29/32

Facility: ISP Pharmaceutical Technology Center, 9165 Rumsey Rd. Columbia, MD 21045

Test Dates: Oct 12 to Nov 24, 2009

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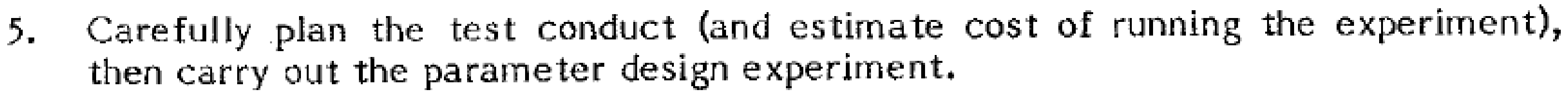
ISP case study



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SUMMARY:

The spray drying portion of the process for API-313 – PVP-29/32 was evaluated in a Taguchi factorial designed experiments that addressed the spray drying gas stream and included all available process control parameters (flow, pressure, temperature, and solvents' humidity) and anticipated extraneous noise factors (32 experiments). Responses include quality attributes of the in-process product (assay/impurities, particle size, particle size distribution, and density), consequential attributes of the product (intermediate residual volatiles) and practical process responses as to the process capacity and equipment fouling tendencies.

ISP case study

5. Carefully plan the test conduct (and estimate cost of running the experiment), then carry out the parameter design experiment.

Background:

The fundamental requirement of any spray drying process is the ability to process powders continuously at steady state conditions with typically short drying residence time. The challenge with any product is to avoid the fouling of the atomizer and/or adhesion of powder to the equipment that disrupts the steady state and results in variability of the powder formation and drying treatment.

The DoE investigated all main aspects of the process. Experimental ranges were established based on the process development history and clinical manufacturing experience of over six years.

Control factors are exhaustive of the process. Noise factors are as anticipated due to climate, lot to lot variability of the one excipient and variation of the process solvent blend ratio.

ISP case study

5. Carefully plan the test conduct (and estimate cost of running the experiment), then carry out the parameter design experiment.

Objective:

The experiments are intended to statistically characterize and quantify the effects of the available control variables on the product and process.

The experiment was evaluated for robustness and predictability using classic Taguchi quality engineering for parameter design.

The results are to support the initial validation of the process and establish a baseline for ongoing quality assurance: to define a process design space that assures product quality and reveal the current optimal target parameters for manufacturing reliability and efficiency.

6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.

S/N analysis enables the following:

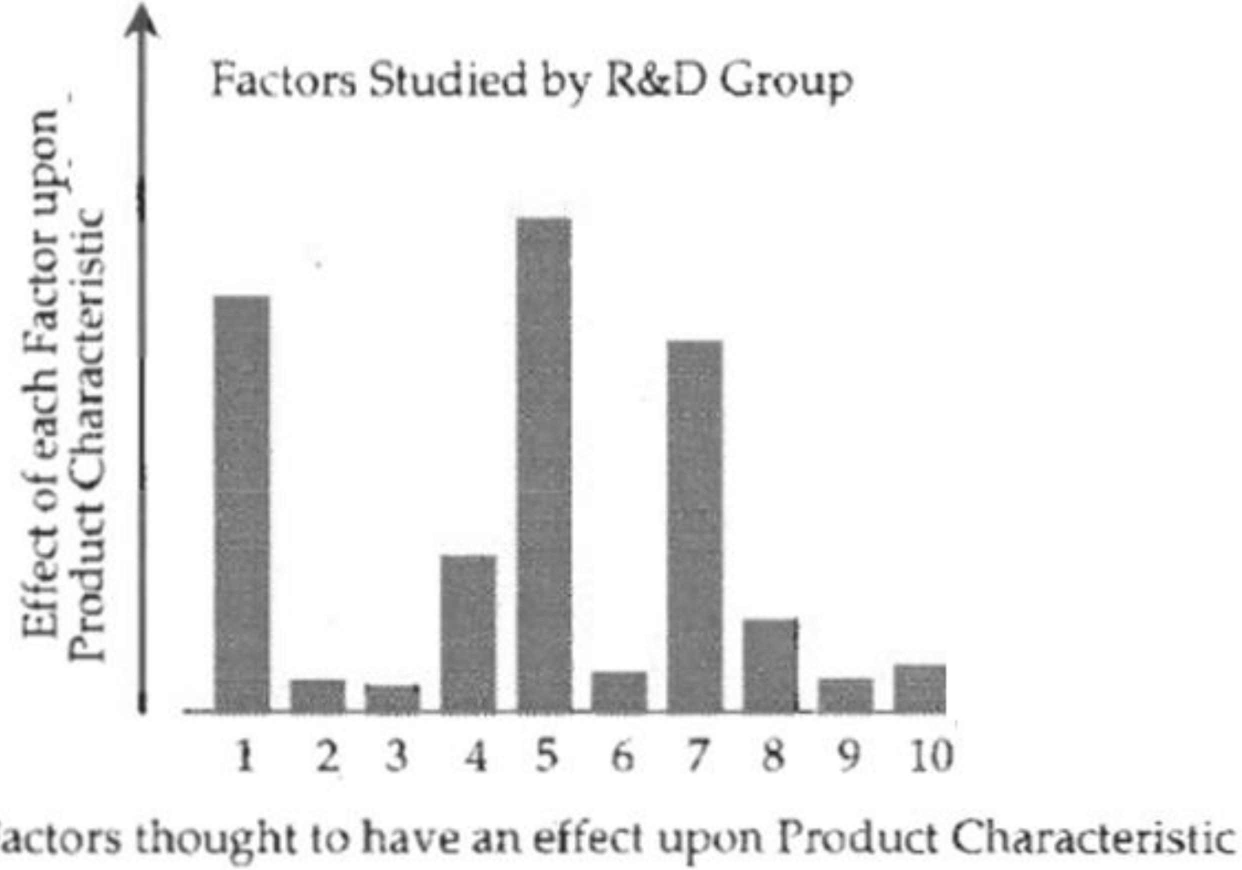
- Control Factor categorization:

CTQ (critical to quality) vs. borderline vs. insignificant

- IF CTQ, then identifies optimum level

(Note: S/N is in decibels – provides a nominal standard)

6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.



Cause and Effect Relationships Studied by R&D

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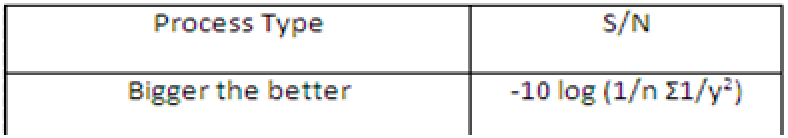
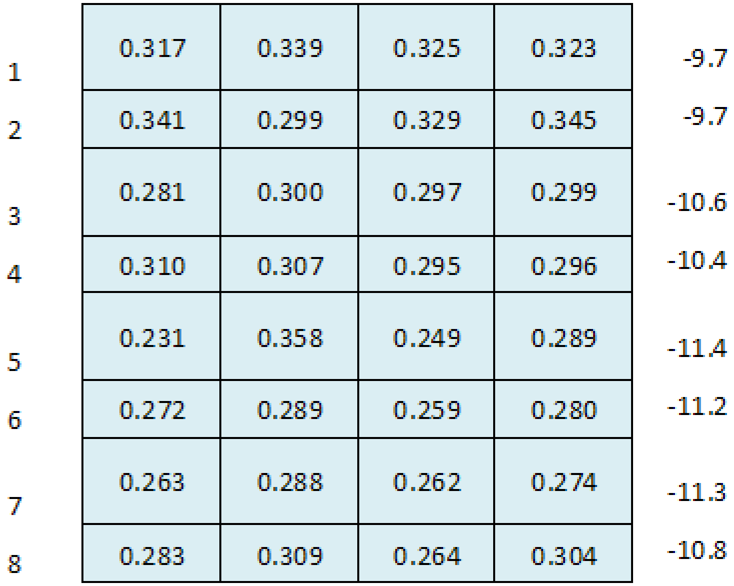
Bulk Density

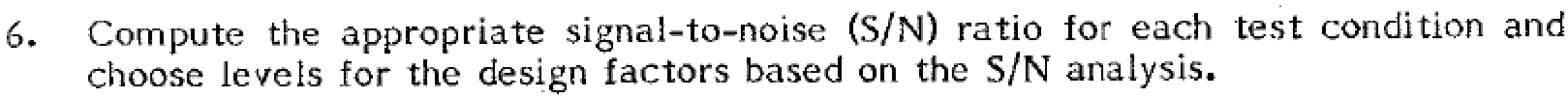


Process Type	S/N
Bigger the better	-10 log (1/n Σ1/y^2)



1	0.317	0.339	0.325	0.323	-9.7
2	0.341	0.299	0.329	0.345	-9.7
3	0.281	0.300	0.297	0.299	-10.6
4	0.310	0.307	0.295	0.296	-10.4
5	0.231	0.358	0.249	0.289	-11.4
6	0.272	0.289	0.259	0.280	-11.2
7	0.263	0.288	0.262	0.274	-11.3
8	0.283	0.309	0.264	0.304	-10.8

ISP case study



6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.

Factor A - Concentration

	$\overline{S/N}$	CF→ Treatment ↓	A
1	-9.7	1st	1
2	-9.7	2nd	1
3	-10.6	3rd	1
4	-10.4	4th	1
5	-11.4	5th	2
6	-11.2	6th	2
7	-11.3	7th	2
8	-10.8	8th	2

Factors/ Levels	A
1	-10.1
2	-11.2

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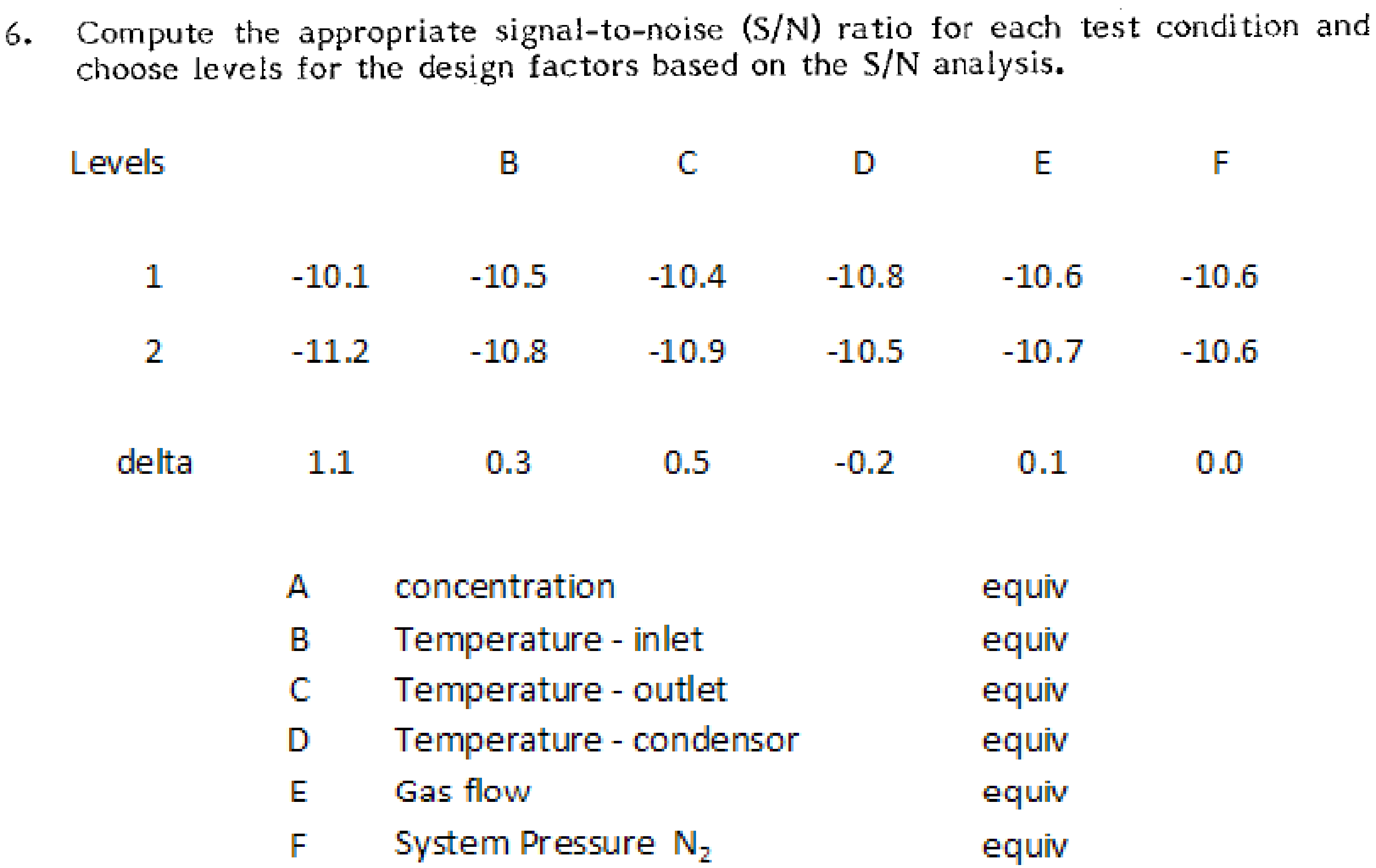
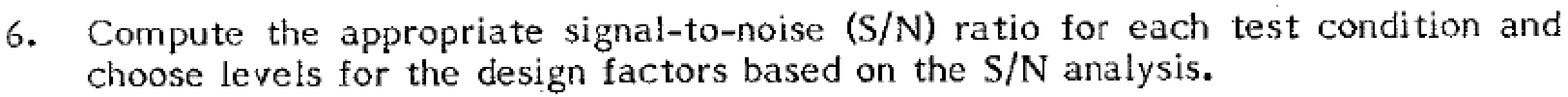


6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.

Levels		B	C	D	E	F
1	-10.1	-10.5	-10.4	-10.8	-10.6	-10.6
2	-11.2	-10.8	-10.9	-10.5	-10.7	-10.6
delta	1.1	0.3	0.5	-0.2	0.1	0.0

A	concentration	equiv
B	Temperature - inlet	equiv
C	Temperature - outlet	equiv
D	Temperature - condensor	equiv
E	Gas flow	equiv
F	System Pressure N_2	equiv

ISP case study



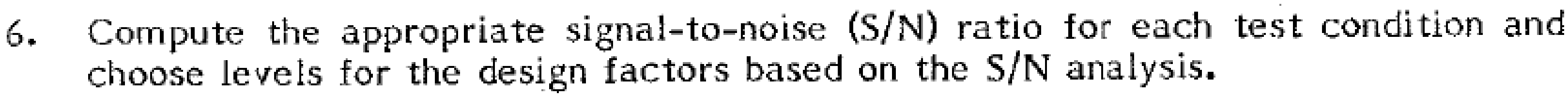
6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.

Pressure Differential

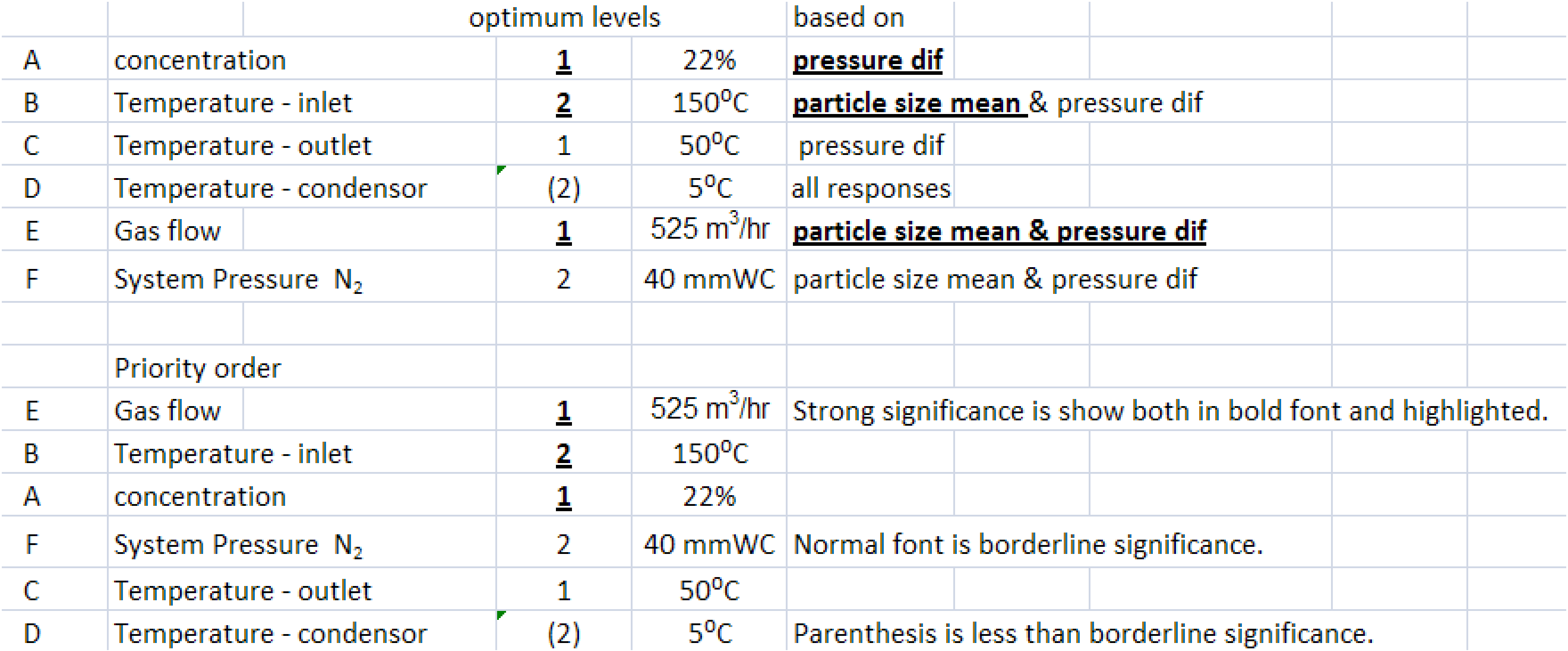
			S/N			
Factors/ Levels	A	B	C	D	E	F
1	-19.8	-23.1	-20.9	-22.1	-22.0	-22.2
2	-23.8	-20.6	-22.7	-22.3	-22.4	-22.5
S/N delta	4.0	-2.5	1.8	0.2	0.4	0.3

A	concentration	1	Low	significant
B	Temperature - inlet	2	High	borderline
C	Temperature - outlet	1	Low	borderline
D	Temperature - condensor			equiv
E	Gas flow			equiv
F	System Pressure N_2			equiv

ISP case study



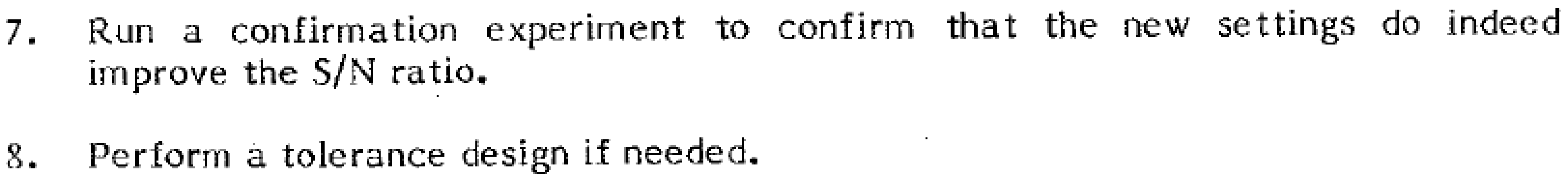
6. Compute the appropriate signal-to-noise (S/N) ratio for each test condition and choose levels for the design factors based on the S/N analysis.



		optimum levels		based on
A	concentration	**1**	22%	**pressure dif**
B	Temperature - inlet	**2**	150^{0}C	**particle size mean** & pressure dif
C	Temperature - outlet	1	50^{0}C	pressure dif
D	Temperature - condensor	(2)	5^{0}C	all responses
E	Gas flow	**1**	525 m^3/hr	**particle size mean & pressure dif**
F	System Pressure N_2	2	40 mmWC	particle size mean & pressure dif
	Priority order			
E	Gas flow	**1**	525 m^3/hr	Strong significance is show both in bold font and highlighted.
B	Temperature - inlet	**2**	150^{0}C	
A	concentration	**1**	22%	
F	System Pressure N_2	2	40 mmWC	Normal font is borderline significance.
C	Temperature - outlet	1	50^{0}C	
D	Temperature - condensor	(2)	5^{0}C	Parenthesis is less than borderline significance.

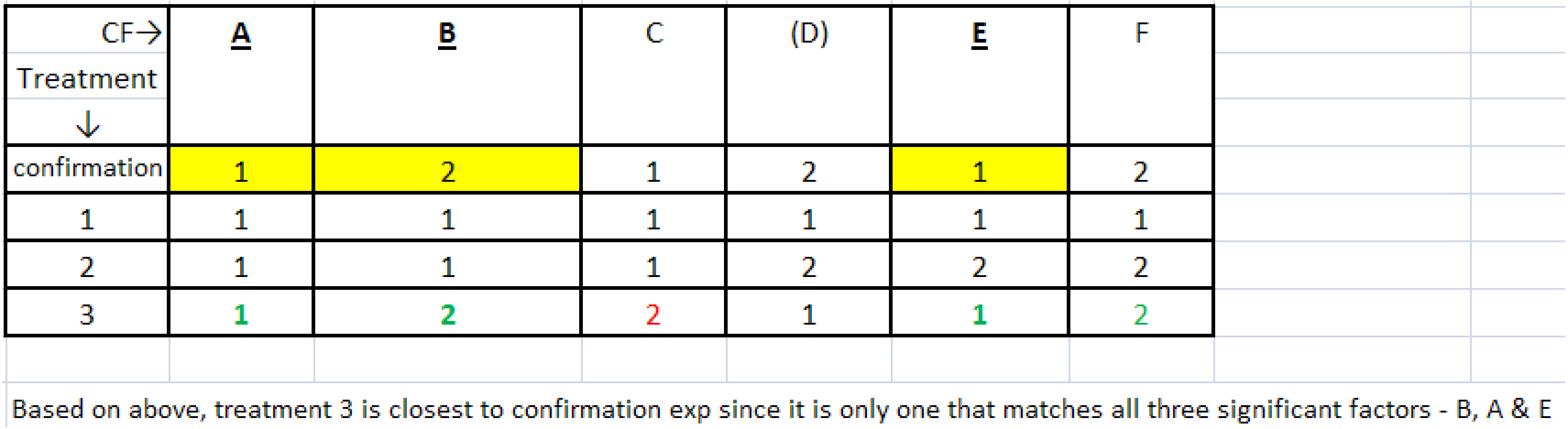
* Strong significance is show both in bold font and underlined. Normal font is borderline significance. Parenthesis is less than borderline significance.

ISP case study



7. Run a confirmation experiment to confirm that the new settings do indeed improve the S/N ratio.

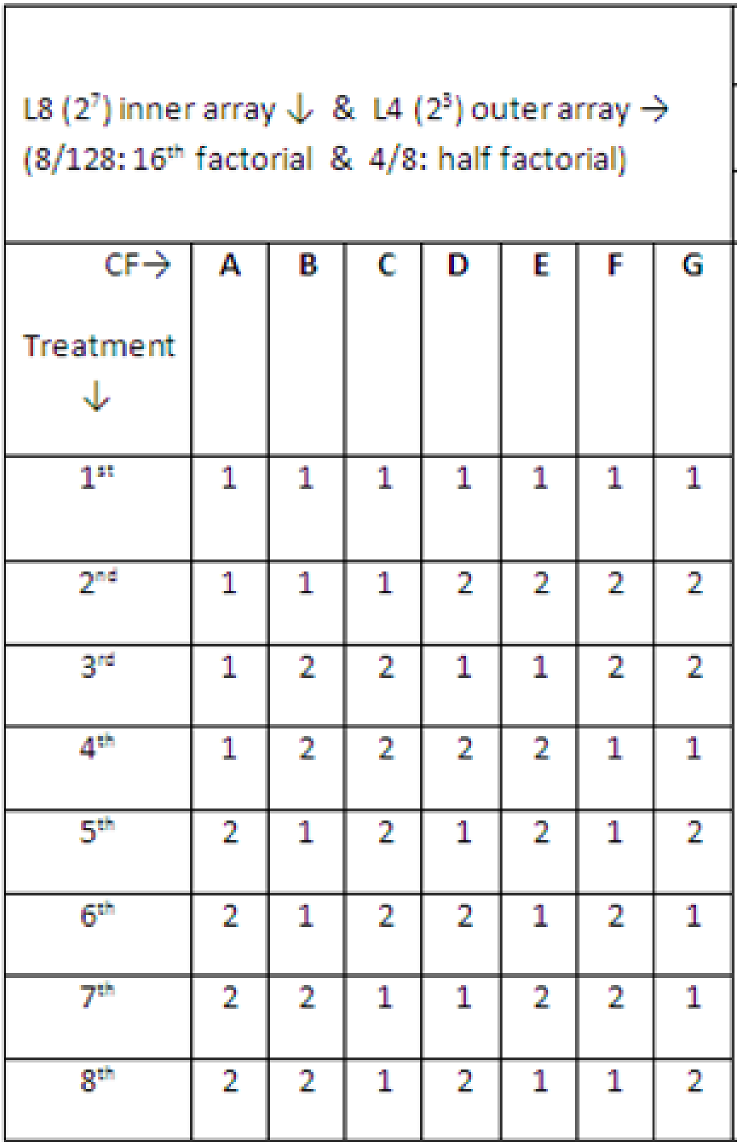
8. Perform a tolerance design if needed.



CF→ Treatment ↓	**A**	**B**	C	(D)	**E**	F
confirmation	1	2	1	2	1	2
1	1	1	1	1	1	1
2	1	1	1	2	2	2
3	1	2	2	1	1	2

Based on above, treatment 3 is closest to confirmation exp since it is only one that matches all three significant factors - B, A & E

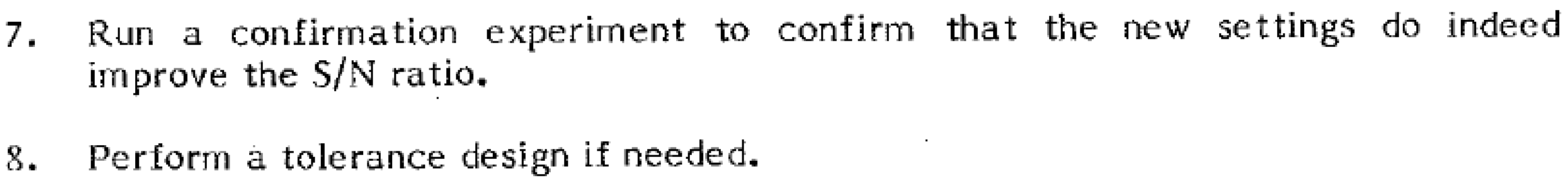
ISP case study



L8 (2^7) inner array ↓ & L4 (2^3) outer array →
(8/128: 16th factorial & 4/8: half factorial)

CF→ Treatment ↓	A	B	C	D	E	F	G
1st	1	1	1	1	1	1	1
2nd	1	1	1	2	2	2	2
3rd	1	2	2	1	1	2	2
4th	1	2	2	2	2	1	1
5th	2	1	2	1	2	1	2
6th	2	1	2	2	1	2	1
7th	2	2	1	1	2	2	1
8th	2	2	1	2	1	1	2

- Control Factors: 7
- Levels: 2
- Total treatments: $2^7 = 128$
- Treatments run: 8
- Factorial: 8/128 = 1/16
- Treatments not needed: 120
- Probability: 120 >>> 8



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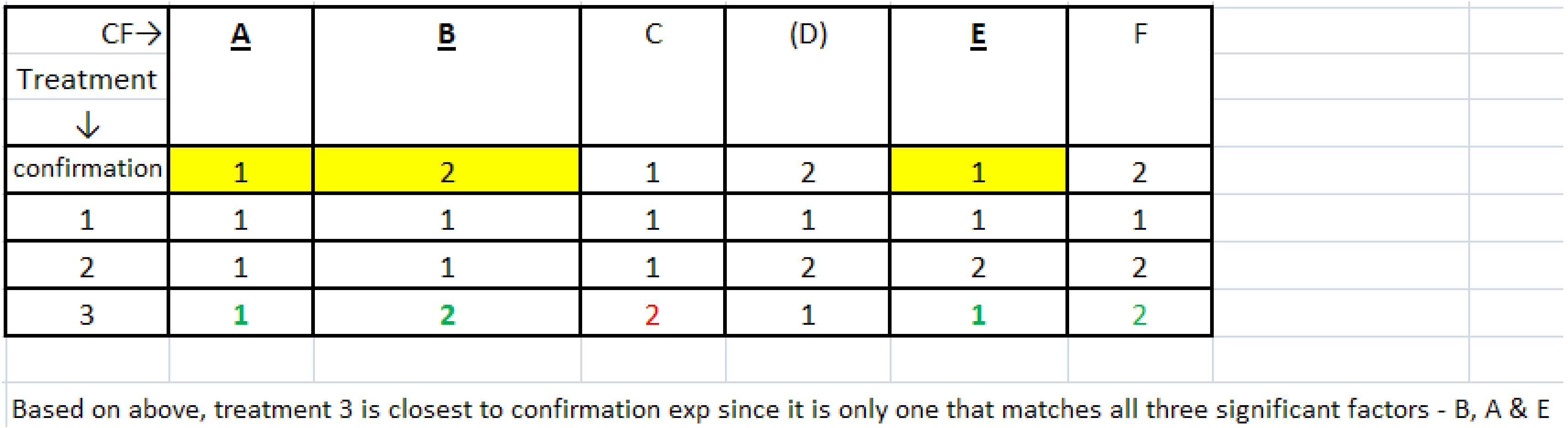
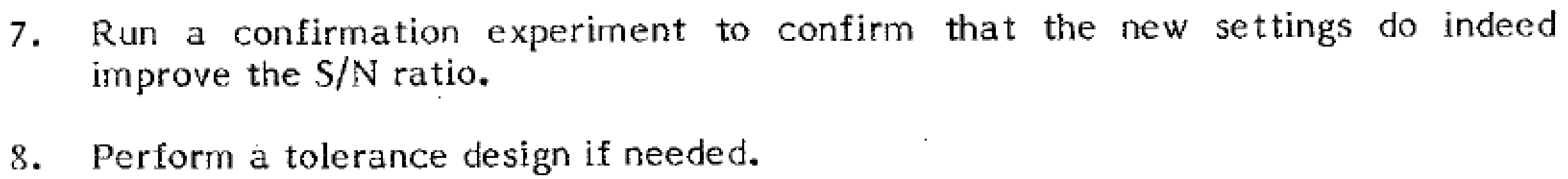


CF→ Treatment ↓	**A**	**B**	C	(D)	**E**	F
confirmation	1	2	1	2	1	2
1	1	1	1	1	1	1
2	1	1	1	2	2	2
3	1	2	2	1	1	2

Based on above, treatment 3 is closest to confirmation exp since it is only one that matches all three significant factors - B, A & E

ISP case study



7. Run a confirmation experiment to confirm that the new settings do indeed improve the S/N ratio.

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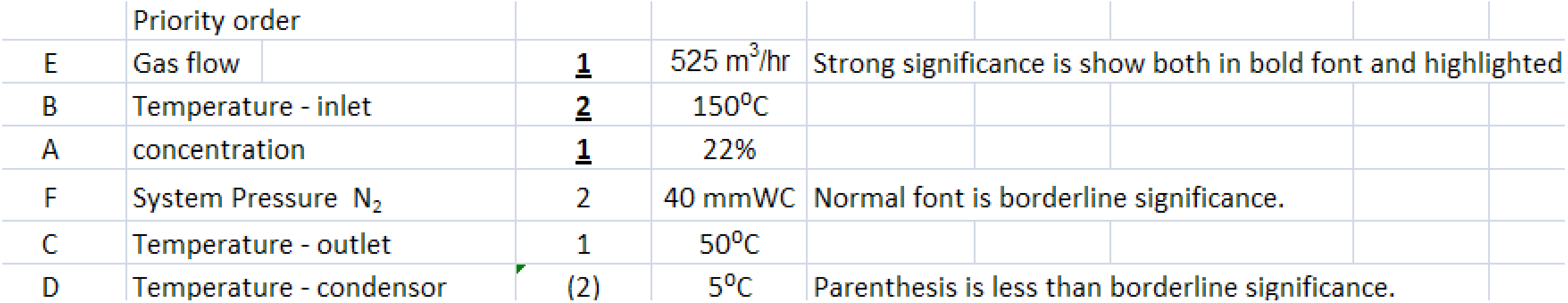
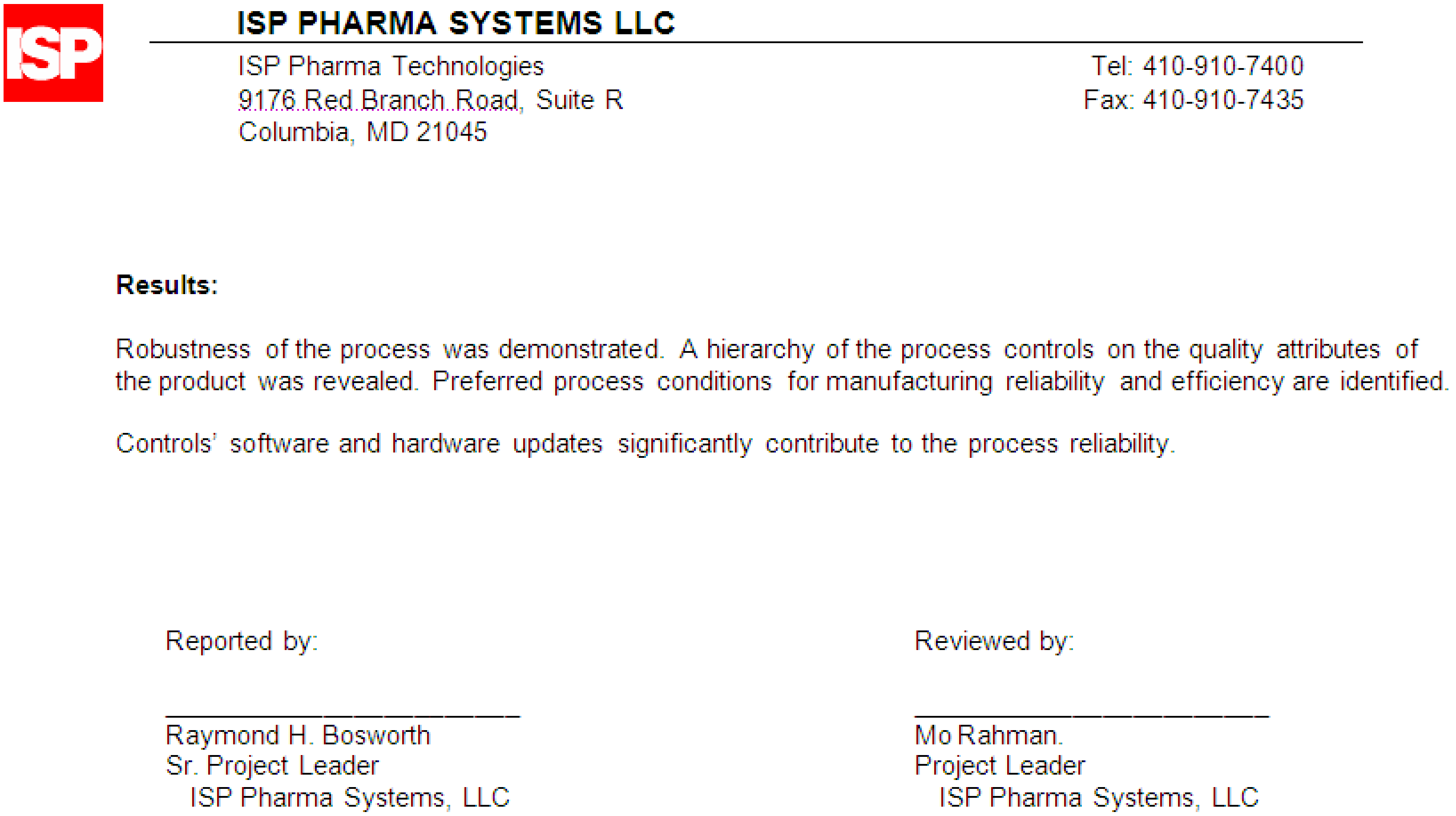


	Priority order			
E	Gas flow	**1**	525 m^3/hr	Strong significance is show both in bold font and highlighted
B	Temperature - inlet	**2**	150°C	
A	concentration	**1**	22%	
F	System Pressure N_2	2	40 mmWC	Normal font is borderline significance.
C	Temperature - outlet	1	50°C	
D	Temperature - condensor	(2)	5°C	Parenthesis is less than borderline significance.

ISP case study



ISP PHARMA SYSTEMS LLC

ISP Pharma Technologies
9176 Red Branch Road, Suite R
Columbia, MD 21045

Tel: 410-910-7400
Fax: 410-910-7435

Results:

Robustness of the process was demonstrated. A hierarchy of the process controls on the quality attributes of the product was revealed. Preferred process conditions for manufacturing reliability and efficiency are identified.

Controls' software and hardware updates significantly contribute to the process reliability.

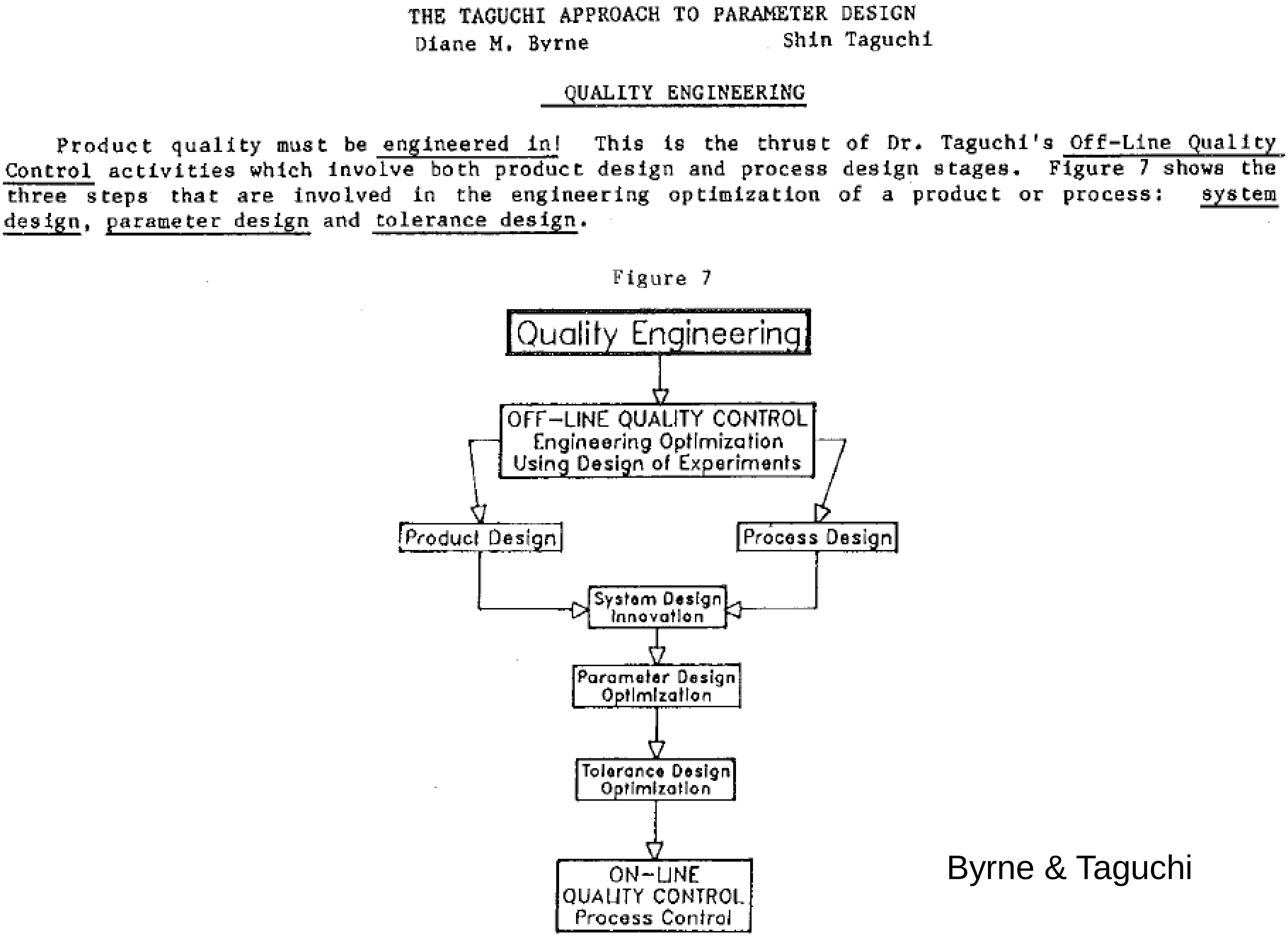
Reported by:

____
Raymond H. Bosworth
Sr. Project Leader
ISP Pharma Systems, LLC

Reviewed by:

____
Mo Rahman.
Project Leader
ISP Pharma Systems, LLC

ISP case study



THE TAGUCHI APPROACH TO PARAMETER DESIGN

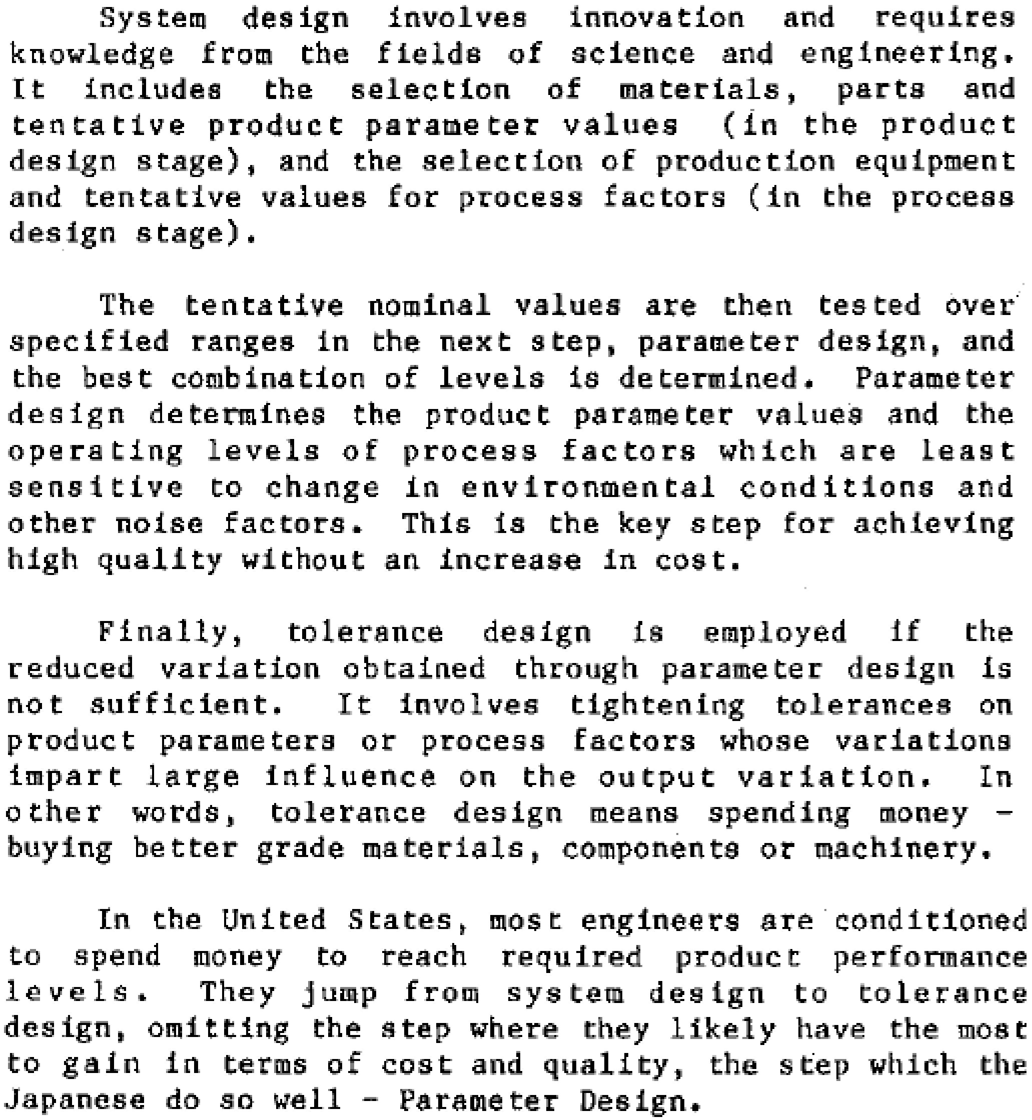
Diane M. Byrne   Shin Taguchi

QUALITY ENGINEERING

Product quality must be engineered in! This is the thrust of Dr. Taguchi's Off-Line Quality Control activities which involve both product design and process design stages. Figure 7 shows the three steps that are involved in the engineering optimization of a product or process: system design, parameter design and tolerance design.

Figure 7

Byrne & Taguchi

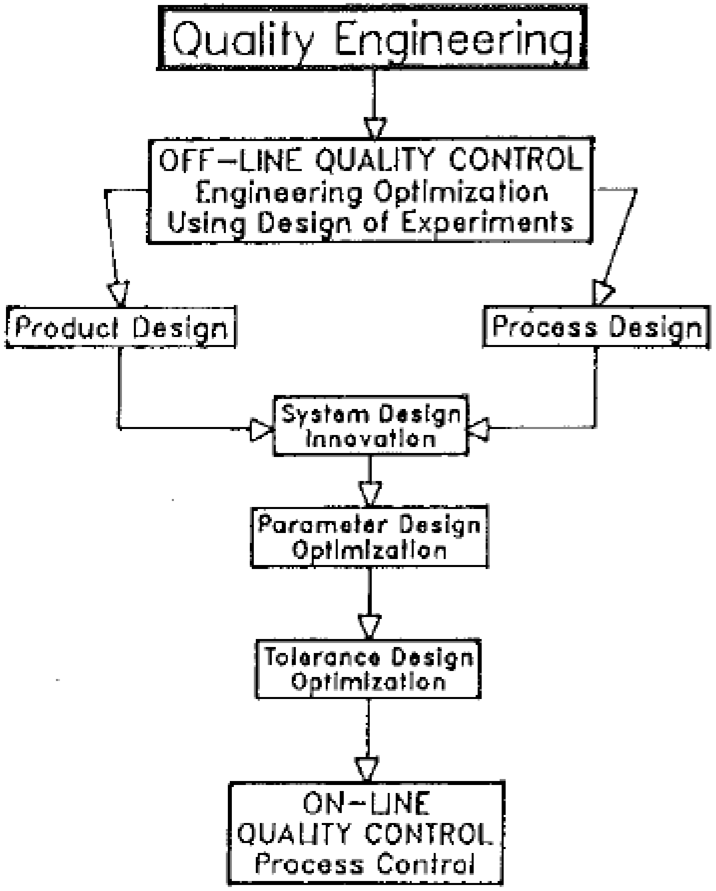


System design involves innovation and requires knowledge from the fields of science and engineering. It includes the selection of materials, parts and tentative product parameter values (in the product design stage), and the selection of production equipment and tentative values for process factors (in the process design stage).

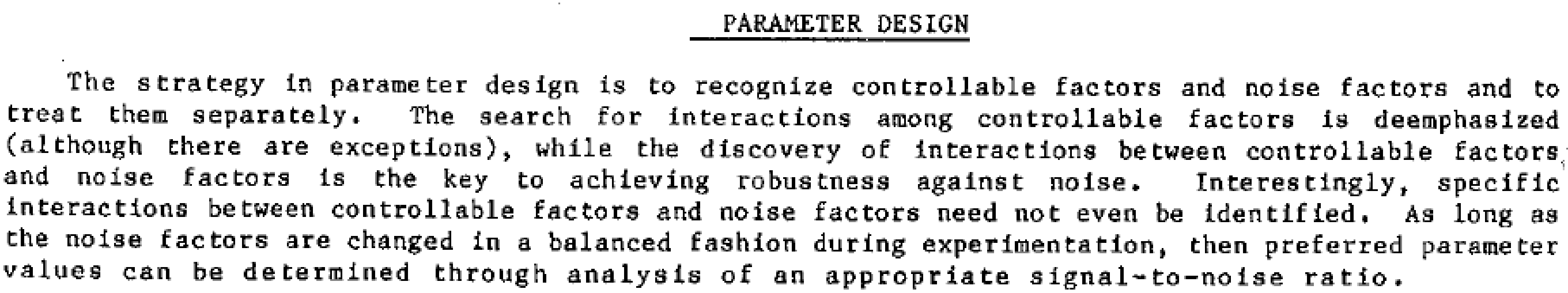
The tentative nominal values are then tested over specified ranges in the next step, parameter design, and the best combination of levels is determined. Parameter design determines the product parameter values and the operating levels of process factors which are least sensitive to change in environmental conditions and other noise factors. This is the key step for achieving high quality without an increase in cost.

Finally, tolerance design is employed if the reduced variation obtained through parameter design is not sufficient. It involves tightening tolerances on product parameters or process factors whose variations impart large influence on the output variation. In other words, tolerance design means spending money - buying better grade materials, components or machinery.

In the United States, most engineers are conditioned to spend money to reach required product performance levels. They jump from system design to tolerance design, omitting the step where they likely have the most to gain in terms of cost and quality, the step which the Japanese do so well - Parameter Design.



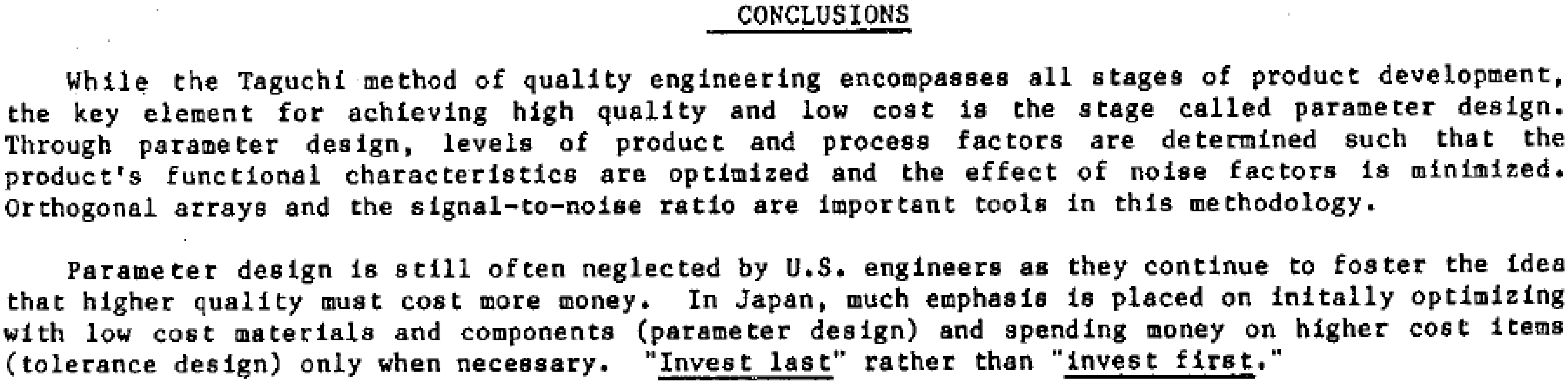
Byrne & Taguchi



PARAMETER DESIGN

The strategy in parameter design is to recognize controllable factors and noise factors and to treat them separately. The search for interactions among controllable factors is deemphasized (although there are exceptions), while the discovery of interactions between controllable factors and noise factors is the key to achieving robustness against noise. Interestingly, specific interactions between controllable factors and noise factors need not even be identified. As long as the noise factors are changed in a balanced fashion during experimentation, then preferred parameter values can be determined through analysis of an appropriate signal-to-noise ratio.

Byrne & Taguchi



CONCLUSIONS

While the Taguchi method of quality engineering encompasses all stages of product development, the key element for achieving high quality and low cost is the stage called parameter design. Through parameter design, levels of product and process factors are determined such that the product's functional characteristics are optimized and the effect of noise factors is minimized. Orthogonal arrays and the signal-to-noise ratio are important tools in this methodology.

Parameter design is still often neglected by U.S. engineers as they continue to foster the idea that higher quality must cost more money. In Japan, much emphasis is placed on initally optimizing with low cost materials and components (parameter design) and spending money on higher cost items (tolerance design) only when necessary. "Invest last" rather than "invest first."

Byrne & Taguchi