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SMART

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Objective of this initiative :

To disseminate the knowledge to many &
to create an interest to implement the knowledge !



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For free circulation only



Investigating a “Non-conformity Report”
(NCR) on
New Product Development (NPD) process



A V Manivannan (AVM)
Founder & Managing partner

Investigating an NCR on NPD process with Statistical evaluations

NEW PROGRAM



NPD TEAM

SUPPLIERS RESOURCES



Audit

You are working in a Tier 1 organization, producing Shafts for Automotive application. You used to receive the product drawings (Shafts) from the OEMs and develop the parts according to the drawings. Your organization's age is 15 years and got certified for ISO / TS 16949 and 3 years back migrated to IATF 16949, also. Now, the Re-certification audit by the Certification body is completed today.

One major NC was raised by the 3rd party auditors on Clause 8.3.4.1, NPD process. The non-conformity observed as ***“there have been many customer related clarifications not solved during the NPD, even after PPAP approval”***. The auditors concluded that your NPD process, with reference to APQP guidelines – is not effective. This was declared & explained by the auditors in the Closing meeting also

Your management (and the MR) agreed on the NCR and your MD mentioned the same kind of concern was raised by a new customer also last week, after their preliminary assessment on QMS. Your top management also have committed to the new customer for a detailed investigation of the NPD process with data based analysis, using appropriate Statistical tools.

The NCR must also be closed within 15 working days from today, as agreed upon by your top management to the auditors



Your top management formed a Task force to investigate this important issue, having you as the leader of the task force (you are working in QA function, as Customer support manager). Along with you one Engineer of Process Engineering, one Sr. officer – Marketing and one Statistician are also deployed as members.

Some background facts

- There are procedures available in the NPD process, with reference to the APQP guidelines and IATF 16949 requirements.
- 2 new products are also under development currently, which need not be covered by the task force, as both are in the very initial stage of NPD and PPAP run is planned only after 4 months.
- CFT approach is there on NPD, for more than 10 years
- Process Engineering head (General Manager) is the APQP team leader for all the CFTs so far (almost 10 years)
- There are 5 major customers. Different model Shafts are being supplied for each Customer.



- The new customer (who had done the assessment few days back) should also be given your investigation report, for the new business.
- APQP related data base is reliable and adequate too.
- Your task force must cover all the 5 customers, at least one part (one model of Shaft) for each customer. This selection must be done at random.
- Preliminary data is collected by your task force on next day itself.
- Excepting the 2 new products under development, all the running products were approved for the PPAP by the customers.

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Investigating an NCR on NPD process with Statistical evaluations

Year	Customer	% of issues un-sorted out by the CFT during NPD
2012	C 1	9
	C 2	12
	C 3	8
	C 4	22
	C 5	21
2013	C 1	29
	C 2	27
	C 3	3
	C 4	29
	C 5	12
2014	C 1	26
	C 2	22
	C 3	12
	C 4	33
	C 5	19
2015	C 1	33
	C 2	19
	C 3	15
	C 4	38
	C 5	16

Year	Customer	% of issues un-sorted out by the CFT during NPD
2016	C 1	8
	C 2	12
	C 3	9
	C 4	34
	C 5	23
2017	C 1	43
	C 2	16
	C 3	11
	C 4	18
	C 5	27
2018	C 1	16
	C 2	7
	C 3	17
	C 4	37
	C 5	23
2019	C 1	30
	C 2	17
	C 3	7
	C 4	22
	C 5	28

Year	Customer	% of issues un-sorted out by the CFT during NPD
2020	C 1	19
	C 2	16
	C 3	13
	C 4	19
	C 5	13

- How will you proceed with your investigation, using the appropriate Statistical tools, to understand the status clearly, to initiate right corrective actions ?
- Please note that the data given here are in %

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Initial (self) assessment



Investigating an NCR on NPD process with Statistical evaluations

Initial (Self) assessment :

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#	Statement	Yes	Need more info	No
1	This organization (Tier 1) is <u>not</u> having the Product design responsibility			
2	<u>None</u> of the Tier 1 organizations will have product design responsibility, since OEM are only responsible for the Product design in every situation			
3	The NCR raised by the 3 rd party auditors on IATF 16949 – Clause 8.3.4.1 is a <u>suitable clause</u> for this NC situation			
4	IATF 16949 – Clause 8 (Operation) is having a close linkage to the guidelines of <u>APQP</u> manual			
5	The task force created (by the top management) is a <u>permanent</u> one in nature for the future days also			



Investigating an NCR on NPD process with Statistical evaluations

Initial (Self) assessment :

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#	Statement	Yes	Need more info	No
6	There are documented procedures present in the organization on the NPD process, as per the APQP guidelines			
7	Process Engineering head, being the APQP team leader also is a good idea, since it has a logic in it			
8	Since the auditors raised a <u>major</u> NCR now, all the products approved already by the customers must undergo a <u>PPAP approval run</u> , after the investigation is completed			
9	Un-solved issues, in the form of <u>Percentage (%)</u> is acceptable			
10	Since the top management themselves are convinced on the NC, <u>Corrective actions</u> shall be initiated, even before the Task force completes their investigation, since this is a <u>Major</u> NC situation			



Initial (Self) assessment

**Our
views**



Investigating an NCR on NPD process with Statistical evaluations

Initial (Self) assessment :

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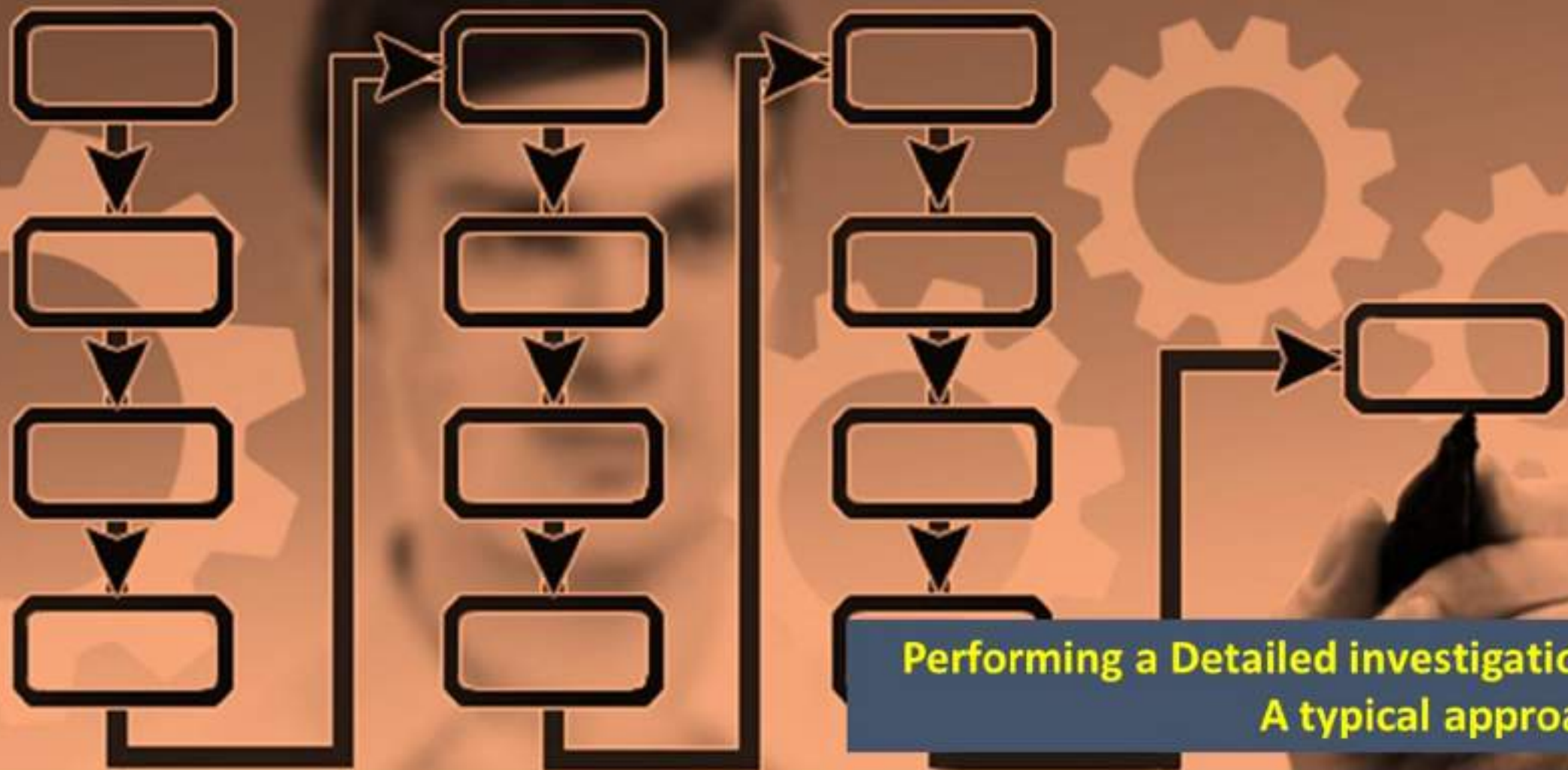


Investigating an NCR on NPD process with Statistical evaluations

Initial (Self) assessment :

#	Statement	Yes	Need more info	No
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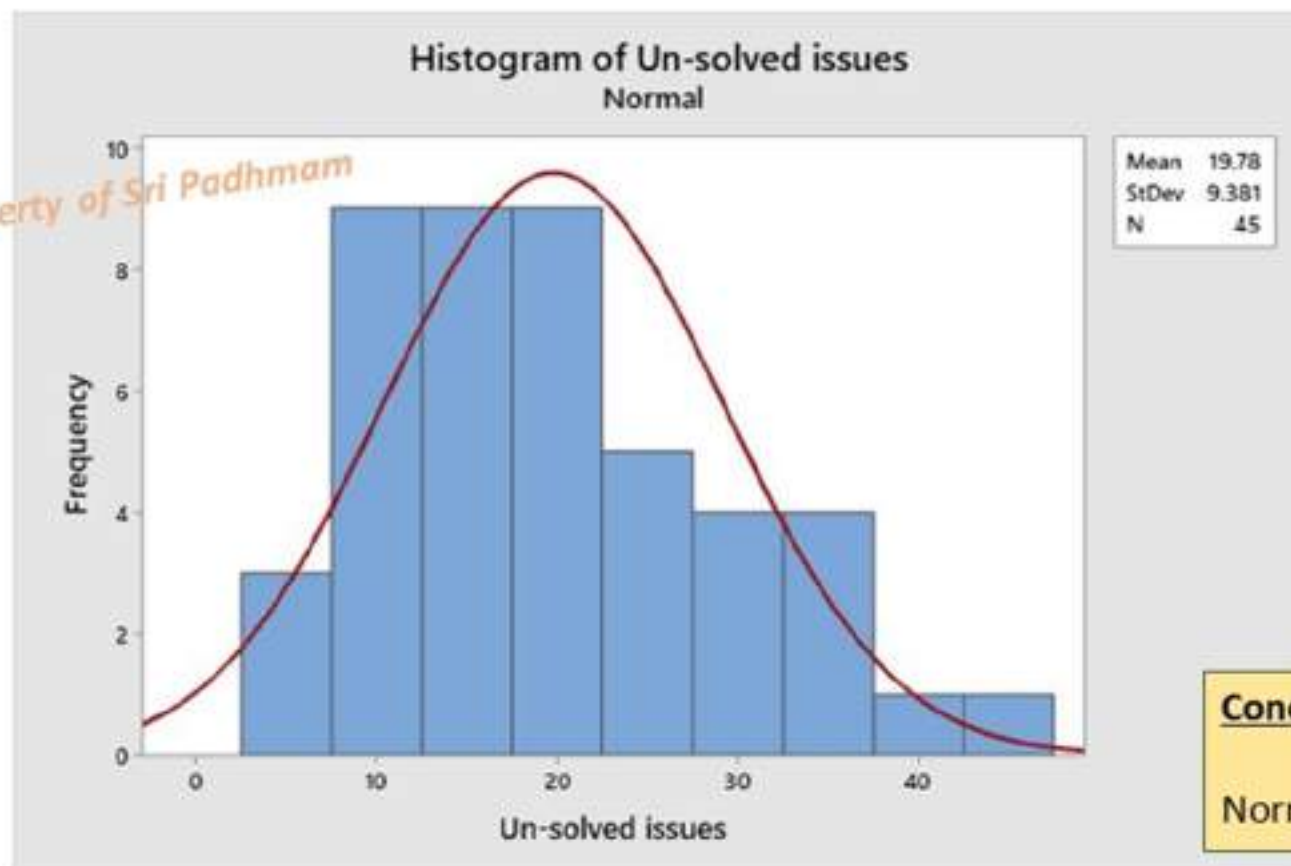
Step 1

Make basic Statistical analysis

% of issues un-sorted by the CFT													
year													
CustomerID	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total	Arith. mean	Median	SSD
C 1	9	29	26	33	8	43	16	30	19	213	23.67	26	11.60
C 2	12	27	22	19	12	16	7	17	16	148	16.44	16	5.90
C 3	8	3	12	15	9	11	17	7	13	95	10.56	11	4.30
C 4	22	29	33	38	34	18	37	22	19	252	28.00	29	7.87
C 5	21	12	19	16	23	27	23	28	13	182	20.22	21	5.72
Total	72	100	112	121	86	115	100	104	80	890			
Arithmetic mean	14.4	20	22.4	24.2	17.2	23	20	20.8	16				
Median	12	27	22	19	12	18	17	22	16				
SSD	6.66	11.87	7.83	10.57	11.12	12.59	11.09	9.26	3.00				

Step 2

Check for data normality through a Histogram analysis

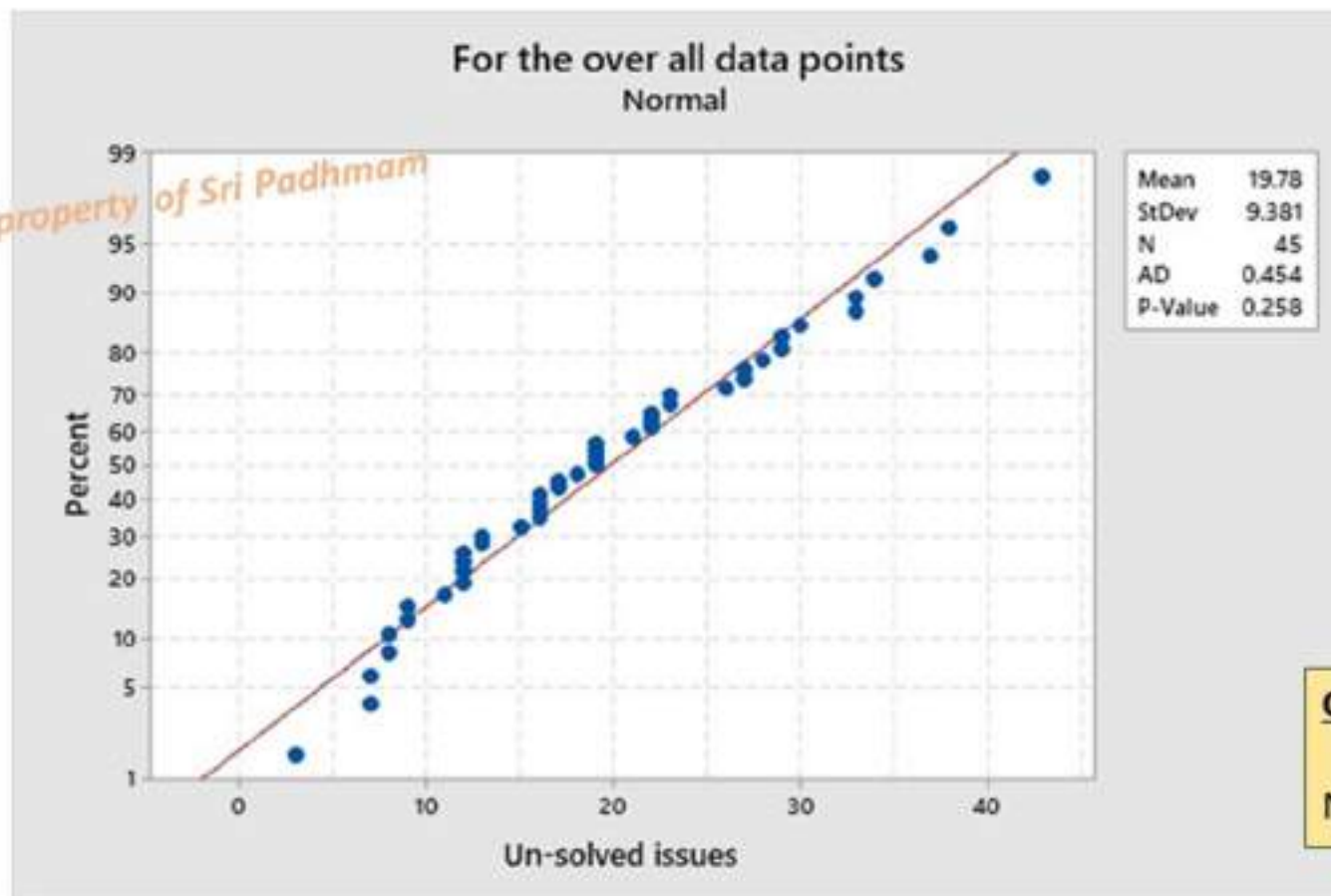


Conclusion :

Normality looks to be acceptable

Step 3

Check for data normality through Normality test and p value check

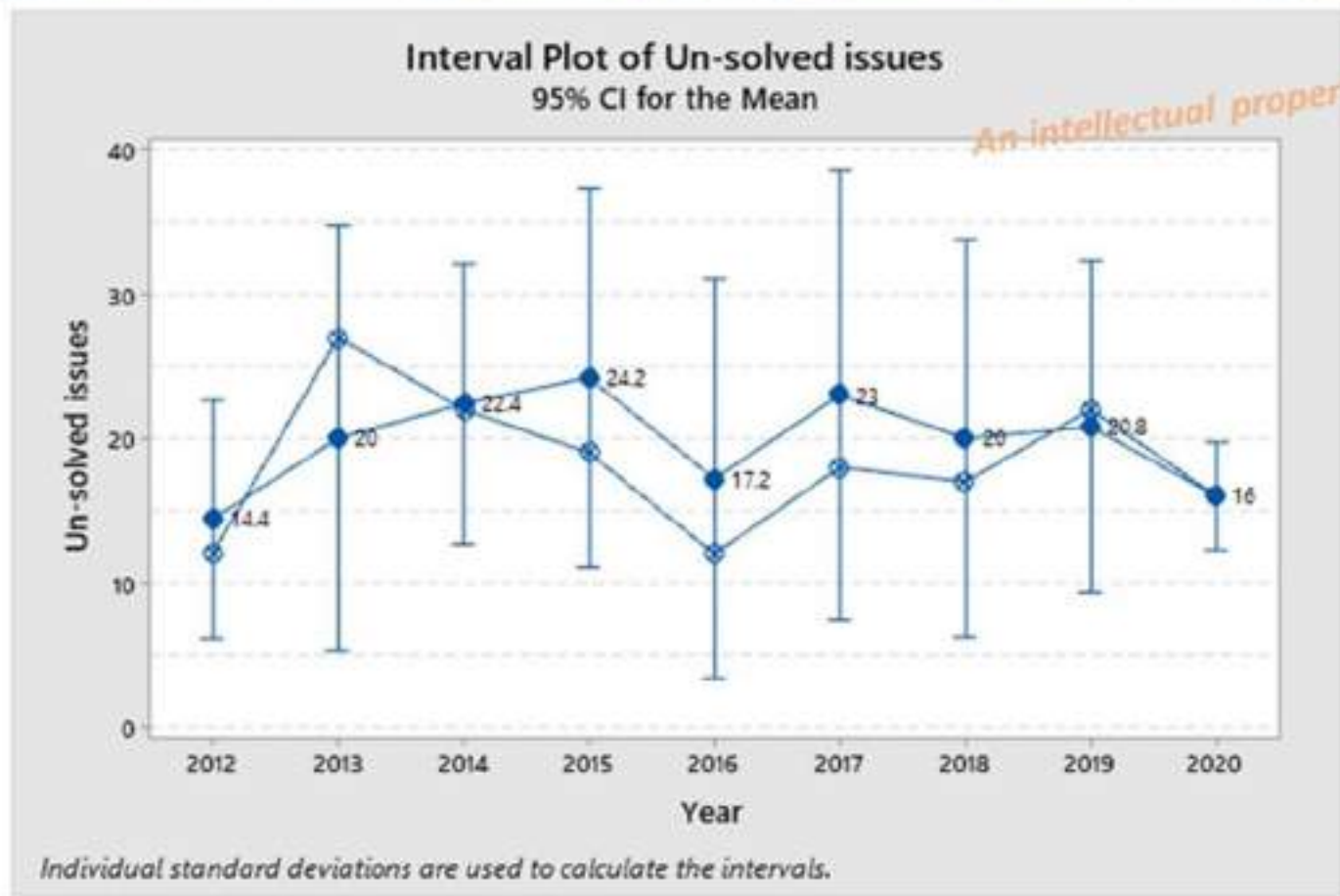


Conclusion :

Normality looks to be acceptable

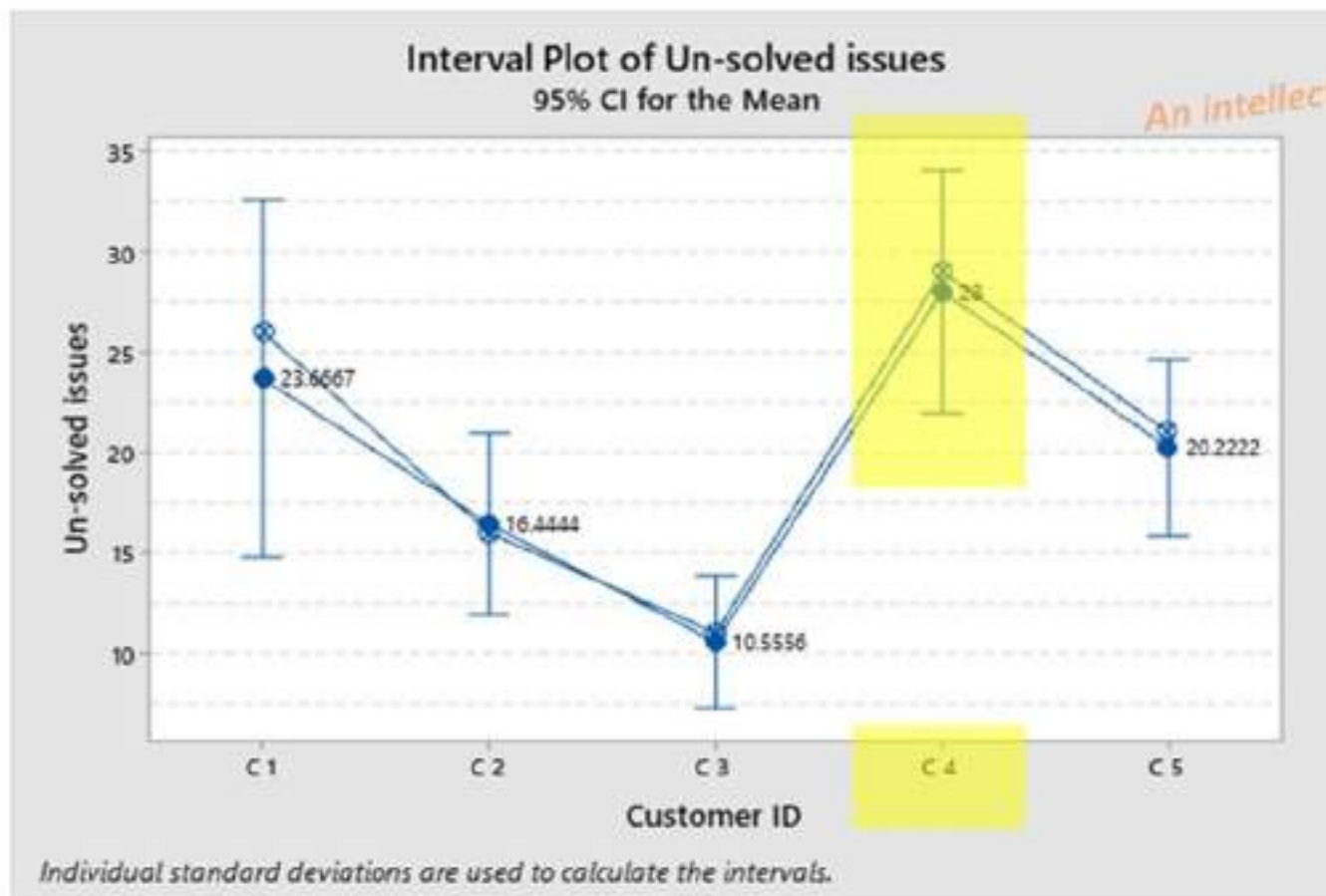
Step 4

Check the data distribution through Interval plot analysis : Year on year basis



Step 5

Check the data distribution through Interval plot analysis : Customers basis



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Step 6 - a

Perform a Hypothesis test to know the Stat. model wrt the years

WORKSHEET 2
One-way ANOVA: Un-solved issues versus Year

Method
 Null hypothesis All means are equal
 Alternative hypothesis Not all means are equal
 Significance level $\alpha = 0.05$
Equal variances were assumed for the analysis.

Factor Information
Factor Levels Values
 Year 9 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Year	8	439.0	54.87	0.58	0.791
Error	36	3432.8	95.36		
Total	44	3871.8			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
9.76502	11.34%	0.00%	0.00%

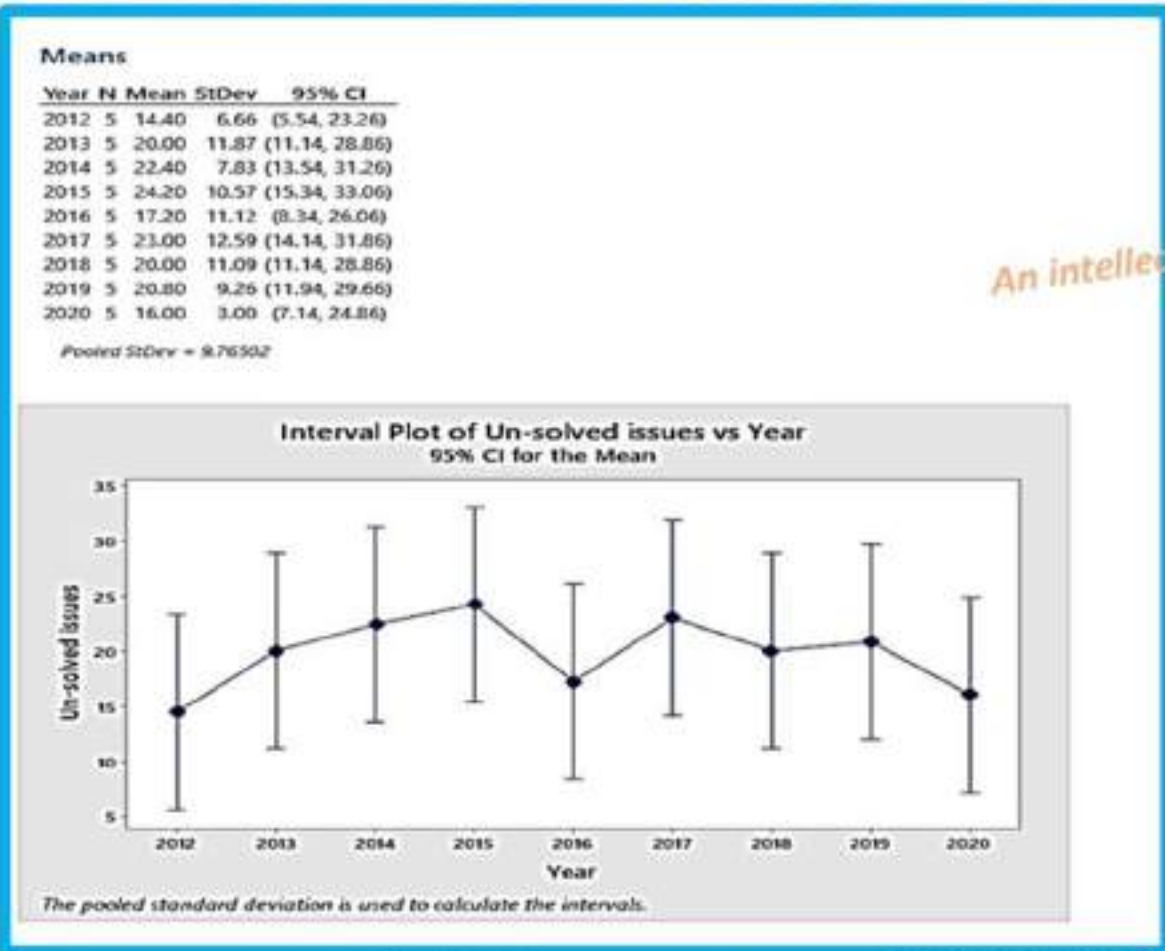
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Continues

Step 6 - b

Perform a Hypothesis test to know the Stat. model wrt the years
(Part of Hypothesis test)

Continues



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Step 7 - a

Perform a Hypothesis test to know the Stat. model wrt the Customer IDs

WORKSHEET 2

One-way ANOVA: Un-solved issues versus Customer ID

Method

Null hypothesis All means are equal
 Alternative hypothesis Not all means are equal
 Significance level $\alpha = 0.05$

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Customer ID	5	C 1, C 2, C 3, C 4, C 5

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Customer ID	4	1612	402.94	7.13	0.000
Error	40	2260	56.50		
Total	44	3872			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
7.51665	41.63%	35.79%	26.12%

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Continues

Step 7 - b

Perform a Hypothesis test to know the Stat. model wrt the Customer IDs
(Part of Hypothesis test)

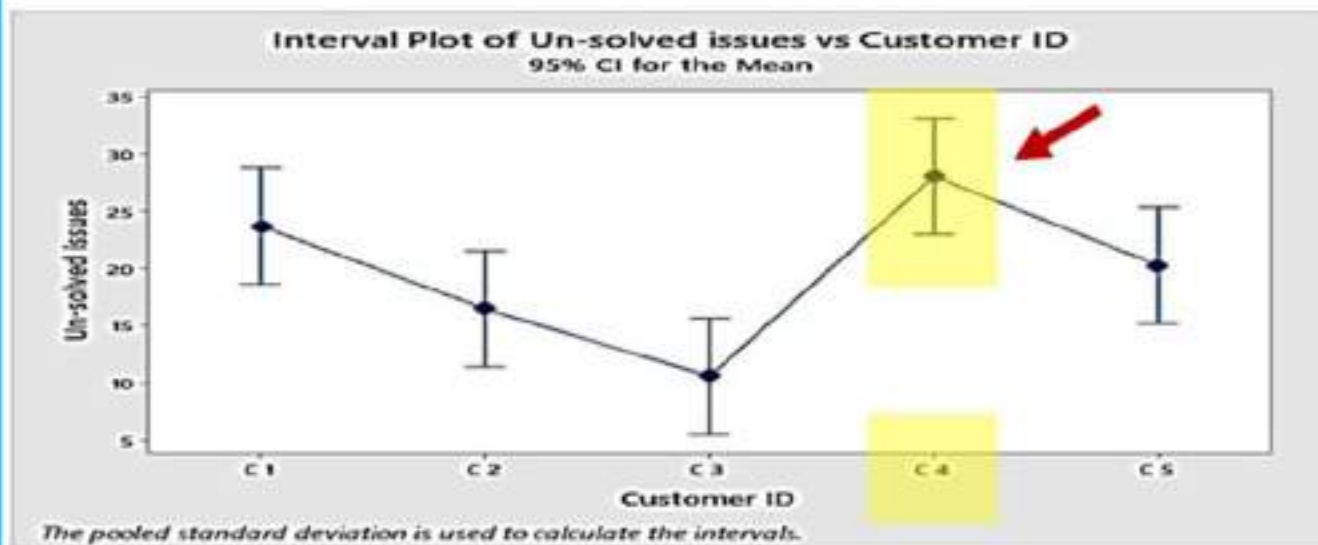
Continues

Means

Customer ID	N	Mean	StDev	95% CI
C 1	9	23.67	11.60	(18.60, 28.73)
C 2	9	16.44	5.90	(11.38, 21.51)
C 3	9	10.56	4.30	(5.49, 15.62)
C 4	9	28.00	7.87	(22.94, 33.06)
C 5	9	20.22	5.72	(15.16, 25.29)

Pooled StDev = 7.51665

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Step 8 - a

Collect and make a basic statistical analysis wrt Customer C 4 - Year on year basis

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Customer ID	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total	Arith. mean	Median	SSD
C 4	22	29	33	38	34	18	37	22	19	252	28.00	29	7.87



Continues

Step 8 - b

Collect and make a basic statistical analysis wrt Customer C 4 - Un-solved issues basis

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Continues

Issues un-solved by the CFT, during NPD		% of issues	Product P 1	Product P 2	Product P 3	Product P 4	Product P 5	Product P 6	Total %
Issue 1	Drawing Spec & Tolerance related	29	0	16	4	9	0	0	29
Issue 2	Insp & Test methods related	36	11	7	4	2	7	5	36
Issue 3	QMS related	6	1	4	0	0	1	0	6
Issue 4	Design feasibility related	21	13	0	0	5	1	2	21
Issue 5	Machining allowance related	8	3	0	2	1	1	1	8
Total %		100							

Step 9 - a

Perform a Hypothesis test to know the Stat. model wrt the product models

Factor Information

Factor Levels Values

Factor 6 Product P 1, Product P 2, Product P 3, Product P 4, Product P 5, Product P 6

Means

Factor	N	Mean	StDev	95% CI
Product P 1	5	5.60	5.98	(1.66, 9.54)
Product P 2	5	5.40	6.62	(1.46, 9.34)
Product P 3	5	2.000	2.000	(-1.938, 5.938)
Product P 4	5	3.40	3.65	(-0.54, 7.34)
Product P 5	5	2.00	2.83	(-1.94, 5.94)
Product P 6	5	1.600	2.074	(-2.338, 5.538)

Pooled StDev = 4.26615

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	5	79.87	15.97	0.88	0.511
Error	24	436.80	18.20		
Total	29	516.67			

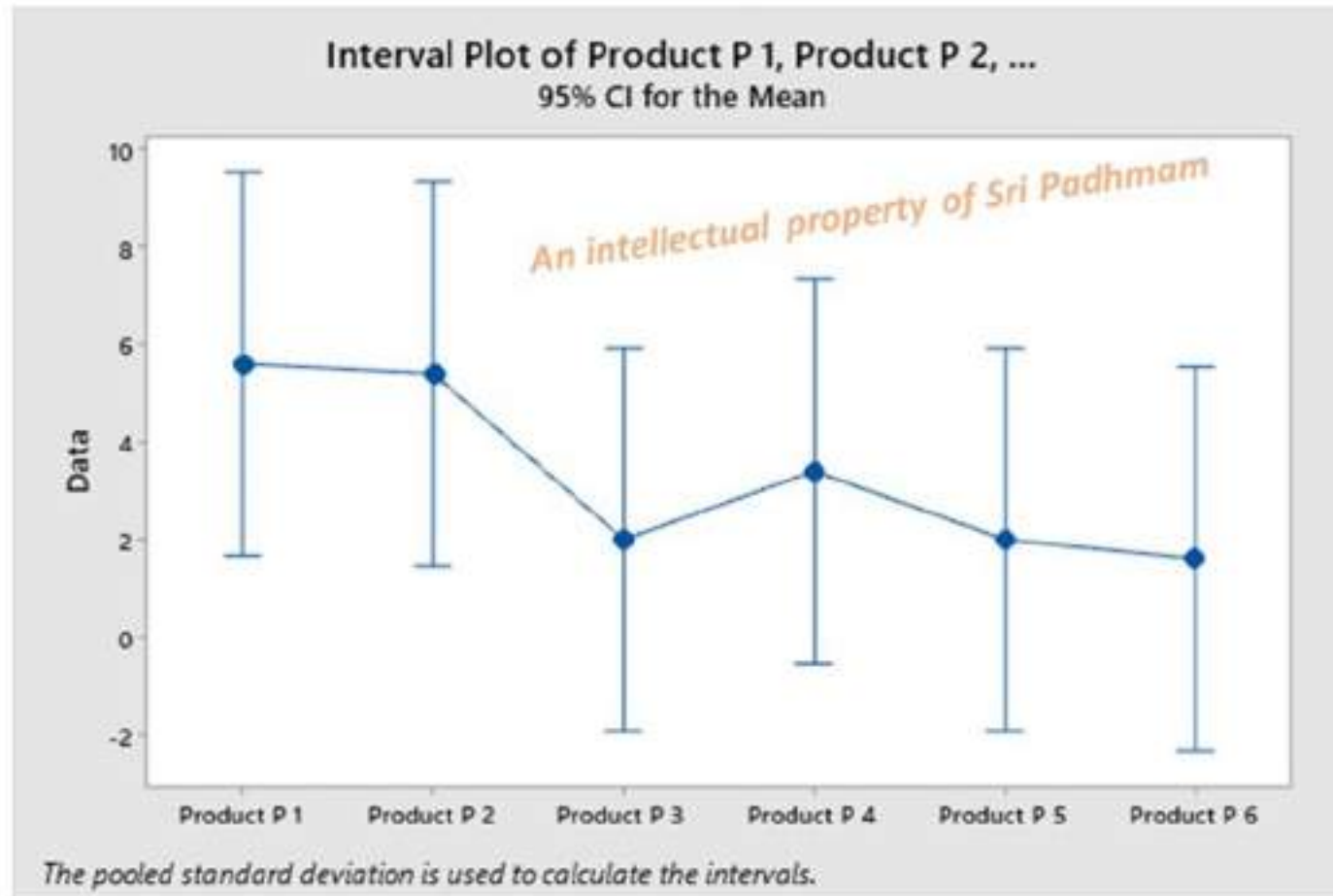
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Continues

Step 9 - b

Make an interval plot to understand the data pattern wrt the Product models

Continues



Step 10

List down the un-solved issues with Customer C 4

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Issues un-solved by the CFT, during NPD		% of issues	Product P 1	Product P 2	Product P 3	Product P 4	Product P 5	Product P 6	Total %
Issue 1	Drawing Spec & Tolerance related	29	0	16	4	9	0	0	29
Issue 2	Insp & Test methods related	36	11	7	4	2	7	5	36
Issue 3	QMS related	6	1	4	0	0	1	0	6
Issue 4	Design feasibility related	21	13	0	0	5	1	2	21
Issue 5	Machining allowance related	8	3	0	2	1	1	1	8
Total %		100							

Step 11

Perform Pareto analysis to make a priority of approach



Step 12

Perform Why-why analysis & determine the CAPAs

Issues un-solved by the CFT, during NPD		% of issues	Why 1	Why 2	Why 3	Why 4	Why 5	Root-cause	Corrective Action	Preventive Action
Issue 1	Insp & Test methods related	36								
Issue 2	Drawing Spec & Tolerance related	29								
Issue 3	Design feasibility related	21								
Issue 4	Machining allowance related	8								
Issue 5	QMS related	6								
Total %		100								

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Complete with Meaningful assumptions (Logical assumptions!)

Investigating an NCR on NPD process with Statistical evaluations



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✓ Deep- analysis : 1

Deep- analysis : 2

#	Statement	Agree	Need more info.	Disagree
1	In Step 1, Customer ID C3, estimated the SD as 4.3 (least of all) is a good sign			
2	In the same step, year 2017 estimates the SD as 12.59 (largest of all) must be statistically significant			
3	Arithmetic mean is always a better indicator, than the Median			
4	Step 2, Histogram is the only way to analyse the Normality of the data points			
5	Step 3, the task force team's decision on Normality (as okay) is acceptable			

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#	Statement	Agree	Need more info.	Disagree
6	The SD (estimated as 9.381) in the Normal probability test, is based on all the data points (45 by count)			
7	Step 4, each stem is having 2 DOTS. One dot is arithmetic mean and the other must be the Mode			
8	Step 6 a, from the P value (0.791), we shall conclude that all the means are equal			
9	Step 7 a, larger the F value (7.13), smaller will the P value (0.00), in every situation			
10	From step 7 b, we shall conclude that the Customer ID C4 is statistically significant and to be analysed as a typical case by the task force			

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#	Statement	Agree	Need more info.	Disagree
11	While analysing the Customer ID C 4, task force shall conclude that there is no one particular product model is Statistically significant (Step 9 a)			
12	The entire situation is on the management process (i.e NPD), and hence Why-why analysis is not recommended, since this is not a technical issue by its very nature			
13	After the root-cause analysis, the task force will have every reason to conclude that there are no documented procedures present for NPD process			
14	Assume that one of the issues (say, Inspection & test related) the task force has identified the Root-cause as “ The customer issues were not sorted-out on time”. This is an acceptable Root-cause			
15	Step 12, assume that there are 2 Root-causes identified by the task force are the SAME root-cause for 2 of the issues. This may be possible (Single Root-cause for 2 problems)			



Investigating an NCR on NPD process with Statistical evaluations



Deep- analysis : 1

✓ Deep- analysis : 2

Choose the best option - 1

Step 1, year 2012 is having the minimum data point of 8 and maximum data point of 22. Whereas in step 6 b, the MiniTab report shows the spread as 5.54 - 23.26. This indicates....

Your options

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a	Those values are from 95 % of Confidence Interval
b	If the similar studies are done, in the similar conditions 100 times, 95 % of the times the individual data points spread would be between 5.54 & 23.26
c	An error margin of 5 % is considered for analysis
d	All the above
e	Only b & c

<p>Choose the best option - 2</p>	<p>Step 7 a, the P value is Zero. This is an indication that</p>
<p>Your options</p>	
<p>a</p>	<p>All the (Customer ID related) means are statistically equal <i>An intellectual property of Sri Padhmam</i></p>
<p>b</p>	<p>Supports the Null hypothesis (Ho)</p>
<p>c</p>	<p>Supports the Alternative hypothesis (Ha)</p>
<p>d</p>	<p>All the above</p>
<p>e</p>	<p>None of the above</p>

<p>Choose the best option - 3</p>	<p>In Step 5, which of the Customer ID is having the <u>largest</u> spread (in terms of un-solved issues) ?</p>
<p>Your options</p>	
<p>a</p>	<p>C 1</p>
<p>b</p>	<p>C 4</p>
<p>c</p>	<p>C 2</p>
<p>d</p>	<p>C 3</p>
<p>e</p>	<p>C 5</p>

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Choose the best option - 4	Which of the Customer ID is having <u>least</u> spread ?
Your options	
a	C 1
b	C 3
c	C 4
d	C 2
e	None of the above

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Choose the best option - 5	Which particular year is the best, in terms of its spread ?
Your options	
a	2012
b	2014
c	2020
d	2018
e	None of the above

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Choose the best option - 6

If we go by the Median statistic, which year is having highest number of un-solved issues ?

Your options

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a 2020

b 2014

c 2019

d 2018

e None of the above

<p>Choose the best option - 7</p>	<p>Step 5, Interval plot analysis goes by</p>
<p>Your options</p>	
<p>a</p>	<p>± 6 SD level</p>
<p>b</p>	<p>± 2 SD level</p>
<p>c</p>	<p>± 3 SD level</p>
<p>d</p>	<p>3.28 SD level</p>
<p>e</p>	<p>None of the above</p>

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Choose the best option - 8

Step 3, which is the direct indicator for the Spread of the data points ? (Refer Normal probability plot)

Your options

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a	N
b	P value
c	Anderson-Darling (AD) value
d	Standard Deviation (SD)
e	Mean

<p>Choose the best option - 9</p>	<p>The task force has used the One-way Anova for determining the statistical significance and Hypothesis study. The other <u>alternative</u> for this analysis <u>would</u> be</p>
<p>Your options</p>	
<p>a</p>	<p>1 sample t test</p>
<p>b</p>	<p>1 proportion test</p>
<p>c</p>	<p>Moods-Median test</p>
<p>d</p>	<p>Chi-square test</p>
<p>e</p>	<p>1 Variance test</p>

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Choose the best option - 10

The One-way Anova test shall be applied, when.....

Your options

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- | | |
|----------|--|
| a | Both X & Y data variables are Discrete in nature |
| b | Both X & Y data variables are Continuous in nature |
| c | When X variable is Discrete in nature and Y variable is Continuous in nature |
| d | When X variable is Continuous in nature and Y variable is Discrete in nature |
| e | None of the above |



Disclaimer

- Knowing the tools & techniques is only a knowledge addition
- This initiative would have added some knowledge, but does not guarantee competence enhancement
- For becoming a competent person, one must work at least 10,000 hours, dedicatedly !
- We wish the same from the learners !

Lean Six Sigma : Foundation workshop

With practical examples, Mr. AVM made the subject very simple & interesting !

Looking forward to take more training in future from him !

Thanks a lot !!

**C O N T A C T
I N F O R M A T I O N**

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