Statistical tools for the statistical monitoring of blood component quality and production

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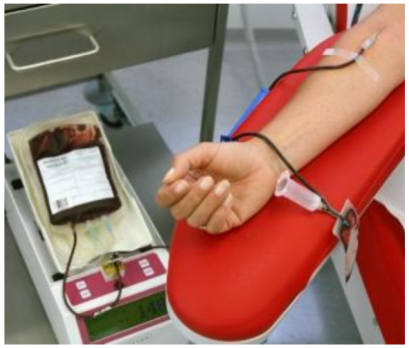
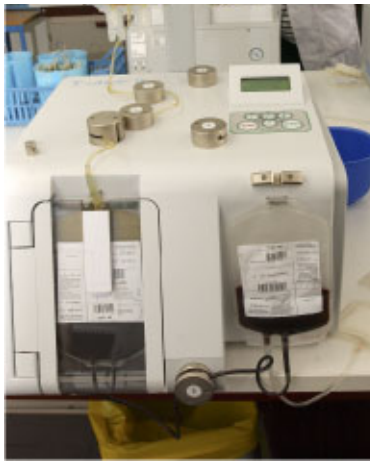
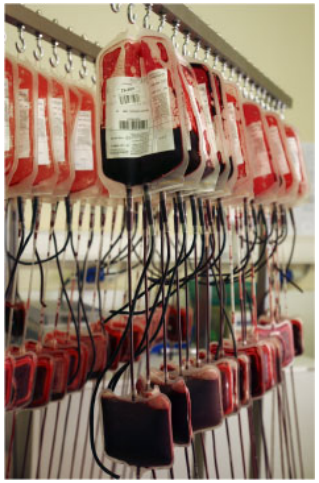
Data in blood component production







date	centri	séparat	Vol ST	Vol CED	Vol BC	Vol P	Hgb/dl CED	Hc CED	1E3 Plaq/mm3 CED	GB Nageot CED	Hgb/unite CED
6/01/15	LDF08	LDF44	475	263	37	290	21.7	66.6	3	0	57.07
6/01/15	LDF08	LDF37	481	284	37	277	19.7	62.7	2	0	55.95
6/01/15	LDF08	LDF40	435	202	51	298	15.4	50.5	27	0	31.11
7/01/15	LDF06	LDF44	483	244	30	321	18	56.8	0	0	43.92
7/01/15	LDF06	LDF43	470	247	36	303	18.4	59.4	0	0	45.45
8/01/15	JOUAN2	LDF39	479	249	51	276	21.1	67.9	2	0	52.54
8/01/15	JOUAN2	LDF44	438	236	38	283	18.6	58.4	0	0	43.90
8/01/15	JOUAN2	LDF40	480	269	55	273	20	63.6	0	0	53.80
9/01/15	LDF08	LDF41	434	227	40	287	18.9	58.5	1	0	42.90
9/01/15	LDF08	LDF40	477	265	35	290	19.5	62.4	0	0	51.68
9/01/15	LDF08	LDF37	471	280	53	257	20.1	63.6	0	0	56.28
13/01/15	LDF56	LDF38	449	258	48	264	19.9	62.2	2	0	51.34
13/01/15	LDF56	LDF40	432	219	38	296	18	57	0	0	39.42
13/01/15	LDF56	LDF37	477	247	53	300	18.8	59.2	1	0	46.44

Thousands of numbers can be collected on a blood component production.

Statistical quality control tools will help to **transform** these **data into information**.

Goal and presentation layout

GOAL

Present a series of tools to characterize the quality of blood component production on the basis on a DATA based monitoring of the process.

Layout

- Review of basic statistical tools
  - Mean, variance, histogram, run chart, normal quantile plot
- Statistical quality control tools
- Control charts
  - Goals and principles of control charts
  - X, Xbar-R, CUSUM, EWMA, p charts and Scan statistics
  - Practical implementation of control charts
- Capability analysis
  - Goals and principles
  - % Non conform, Cpu, Cpl and Cpk indices
- Reception sampling
  - Principles and related ISO norms

Review of some basic but essential statistical concepts and vocabulary when you work with data

Difference between variable and attribute data

Data collected on a blood transformation process can be of 2 types

Quantitative – Measure – (Variable) Data

→ Anything that is measured by an adapted measurement device

→ Cell count, pH, Hgb concentration, weight…

Qualitative – Categorical – Attribute Data

→ Anything that is counted on a "Yes" / "No" basis

→ Visual inspection, test of conformity or not …

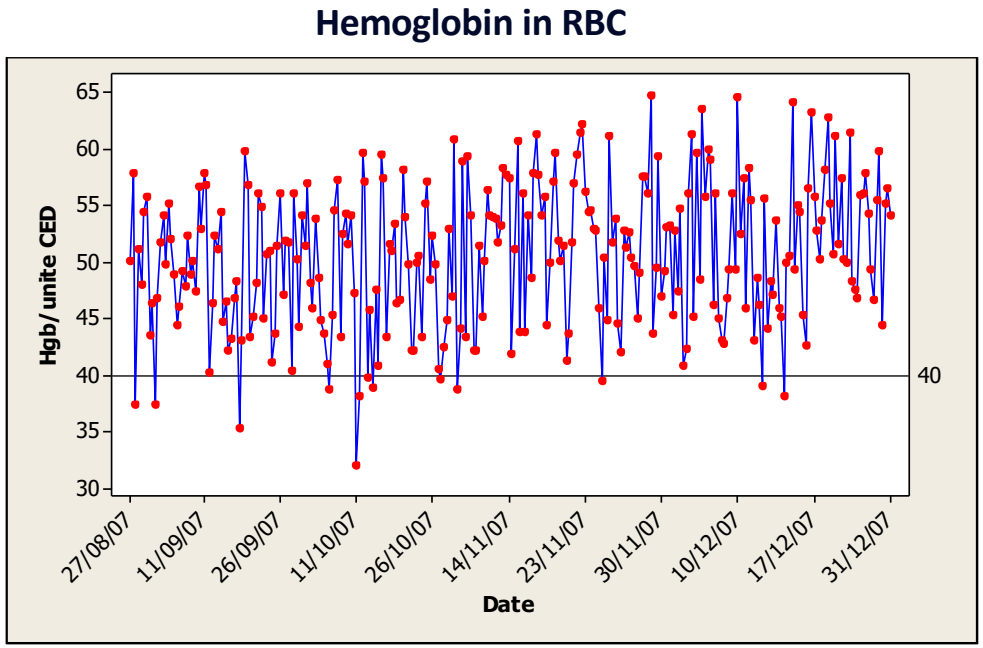
- Quantitative data are usually more informative.
- Attribute data are often easier to collect.

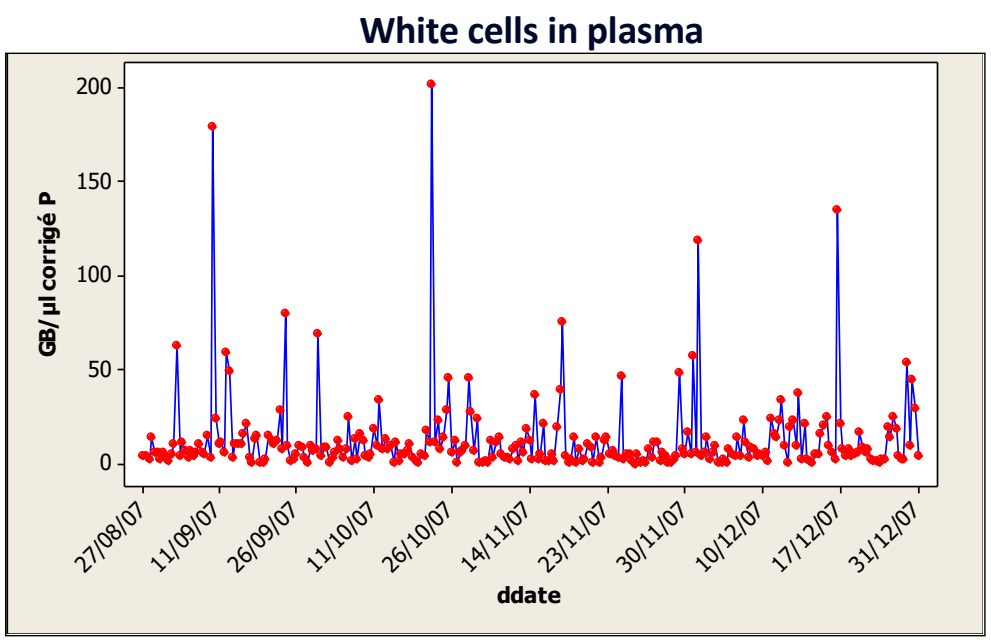
The best tool to analyze the data depends on the type of data we observe.

Let's start with tools for quantitative data.

Run chart : to view the data over time

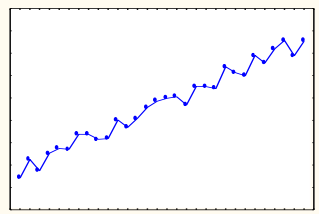
Run Chart = representation of the values of a quantitative variable over time



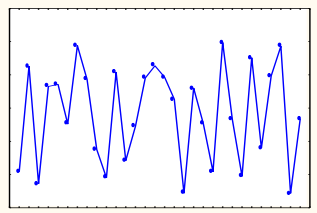


What can one see on a run chart ?

- Position of the process with respect to the specification
- Size of data variability
- Trends in the data
- Outliers values



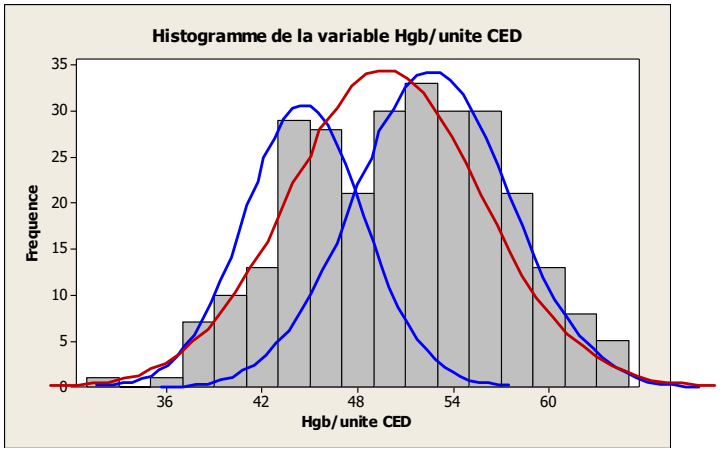
Small variability but high trend

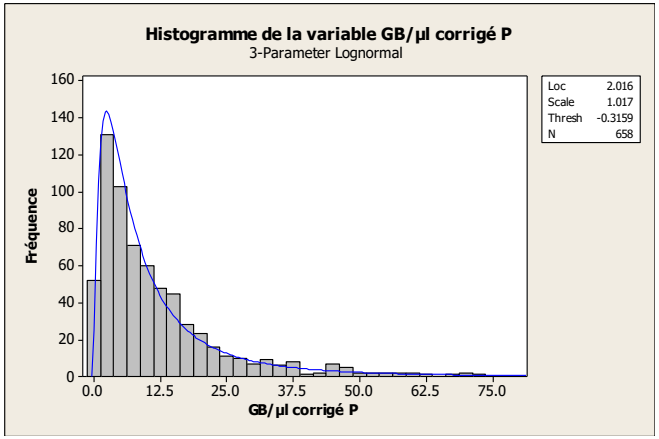


No trend but high variabilty

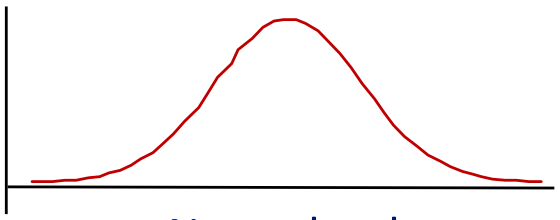
The histogram: to view the data distribution shape

Histogram = representation of the statistical distribution of a quantitative variable

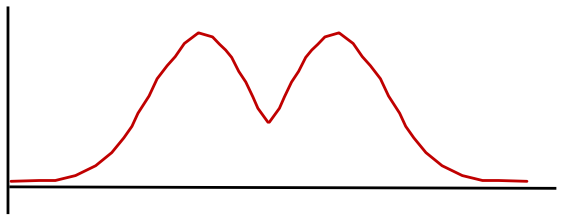




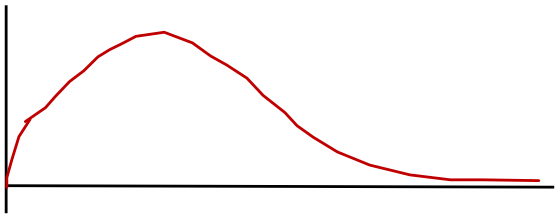
- X axis : classes of data values - Y axis : frequencies of data in each class
- Gives an idea of the position, dispersion of the variable and of the shape the distribution
- Stable for n > 50 – take a number of classes around $\sqrt{n}$



« Normal » shape



“Bimodal”



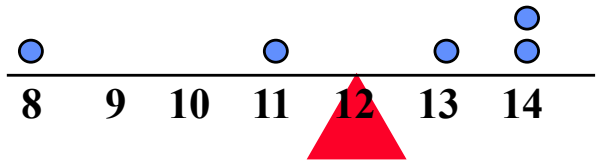
Asymetric

Centrality measures

The **mean** and the **median** are the most common indices used to characterize the position of a variable.

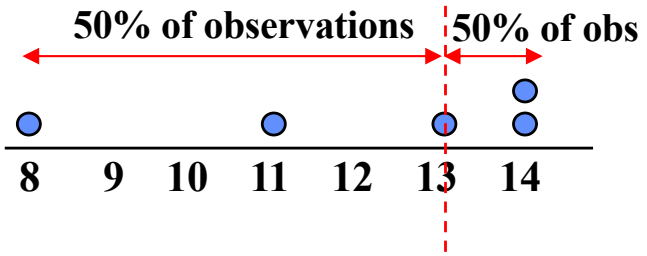
Arithmetic Mean

$$\overline{X} = \frac{1}{N}\sum_{i=1}^{N} X_i = 12$$

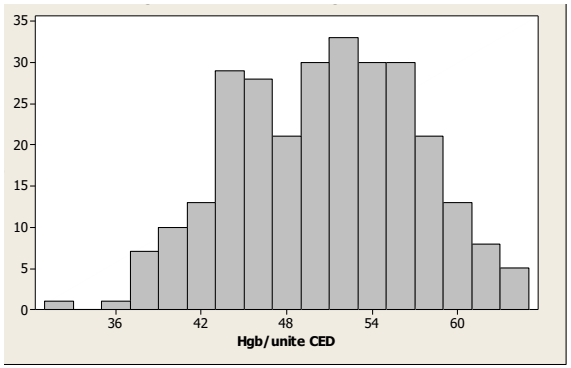


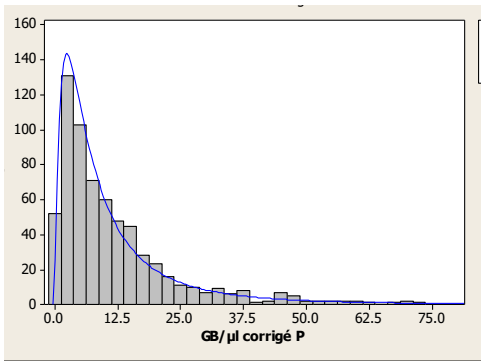
Median or "middle" value

$$q_{0.5}=13$$



- Mean is the index to use when there is no outlier
- The mean is usually compared to the median to judge the asymmetry of the distribution.





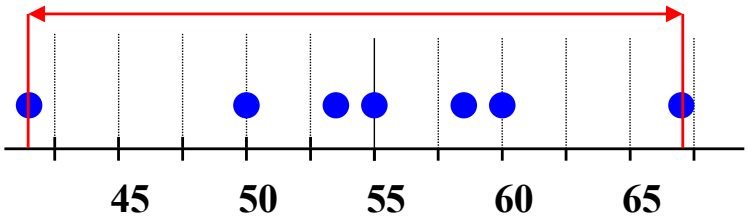
	N	Mean	Median	Range	Std Dev
Hgb/unite CED	679.00	49.38	49.73	35.69	6.32
GB/µl corrigé P	679.00	15.77	8.10	365.90	28.19

Dispersion measures

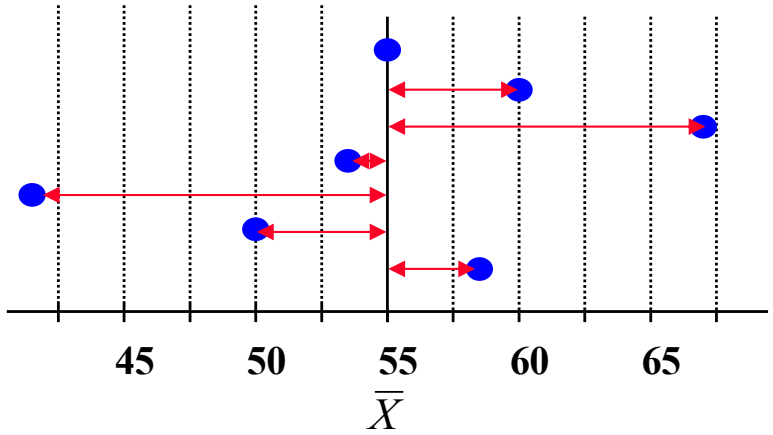
The **range** and the **standard deviation** are the most common indices used to characterize the dispersion or variability of a variable.

Range = $\max(X_i) - \min(X_i)$

Range = 40



Variance and standard deviation



$$s^2 = \frac{1}{N-1}\sum_{i=1}^{N}(\leftrightarrow)^2$$

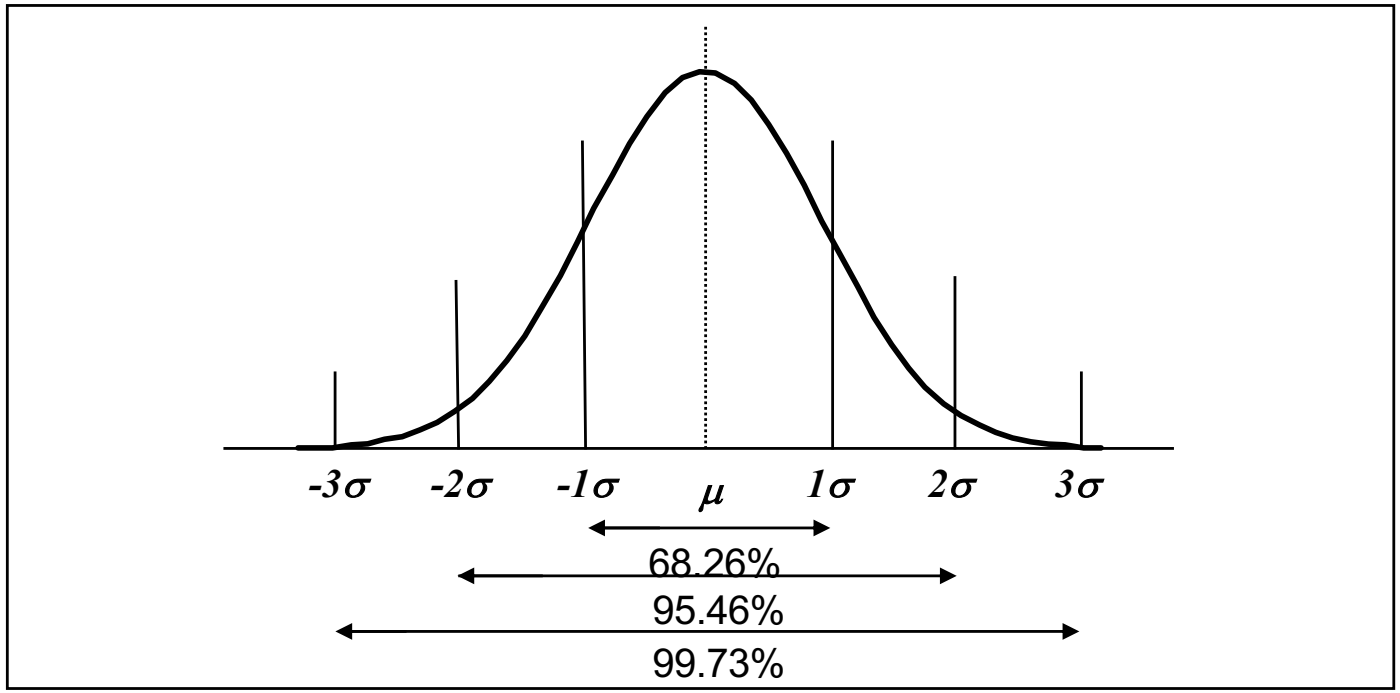
$$= \frac{1}{N-1}\sum_{i=1}^{N}(X_i - \overline{X})^2$$

$$s = \sqrt{s^2} = 7.92$$

- The range is easy to calculate and explain but not very informative
- The standard deviation is more informative but more difficult to interpret. Normality is required.

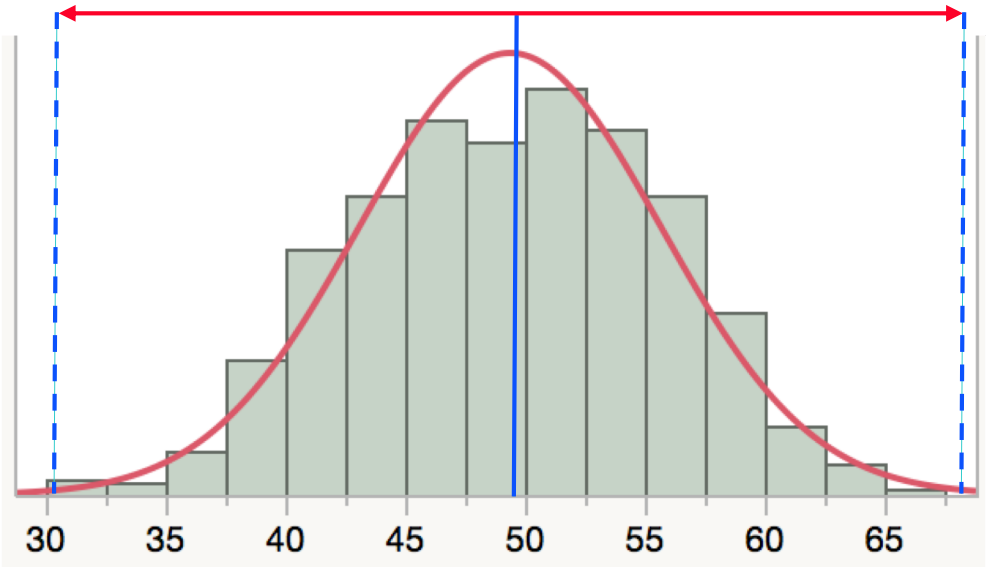
The Normal distribution

- Many biological parameters follow a Normal distribution because they respond to the hypothesis of the central limit theorem.
- In statistical quality control, Normality is taken as default assumption for observed quantitative variables. Transformations of the variable can help to get a Normal.
- The normal distribution is defined by 2 parameters : a position μ and a dispersion σ.
- When data are Normal, 99.73% of the data are in an interval +/- 3σ around μ



Interpreting the standard deviation in Normal variables

	N	Mean	Median	Range	Std Dev
Hgb/unite CED	679.00	49.38	49.73	35.69	6.32

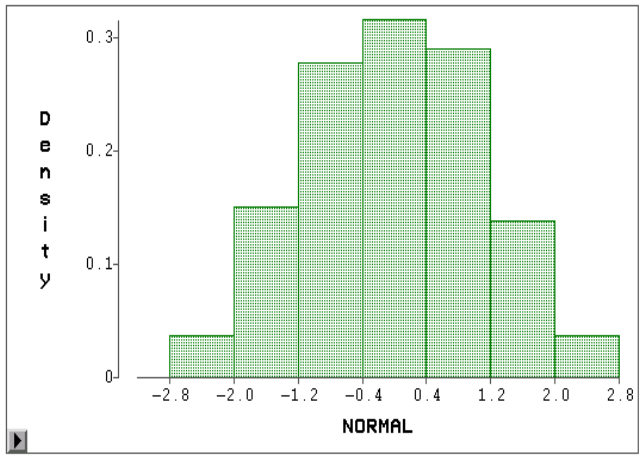


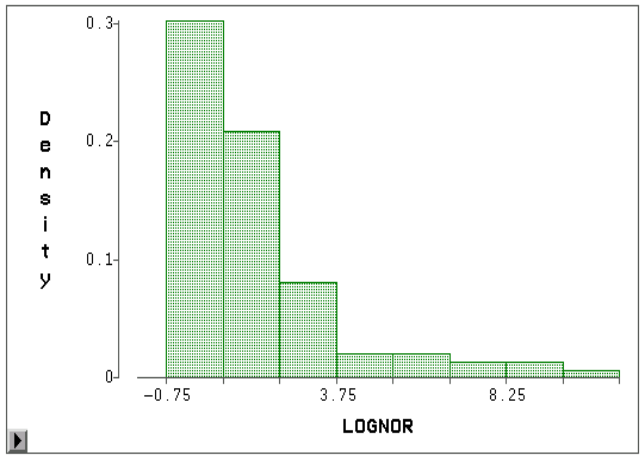
Xbar - 3 S = 49.38 - 3 x 6.32 = 30.42

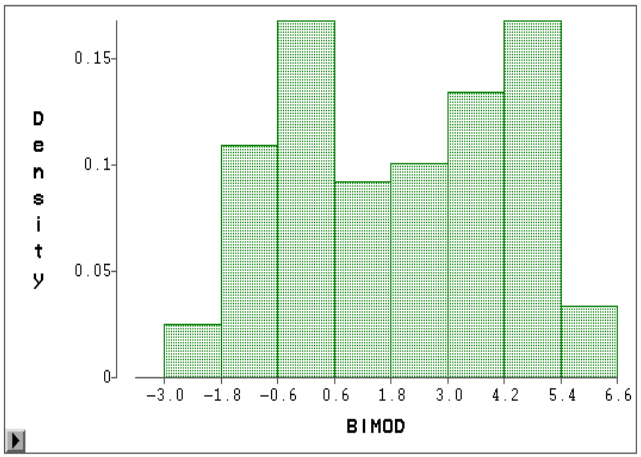
Xbar + 3 S = 49.38 + 3 x 6.32 = 68.34

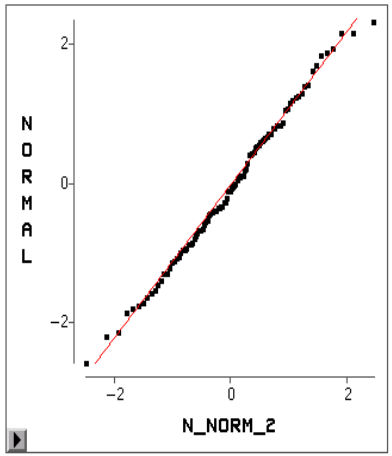
The Normal quantile plot to check the normality of a data set

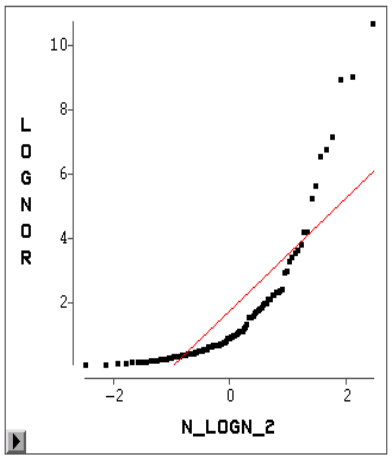
The Normal quantile plot compares a set of data to “ideal” Normal data. Data should be along a line to “accept” normality.

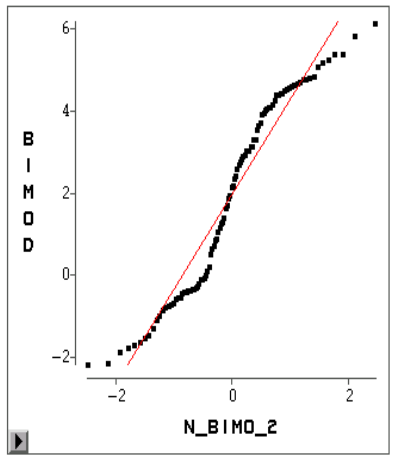






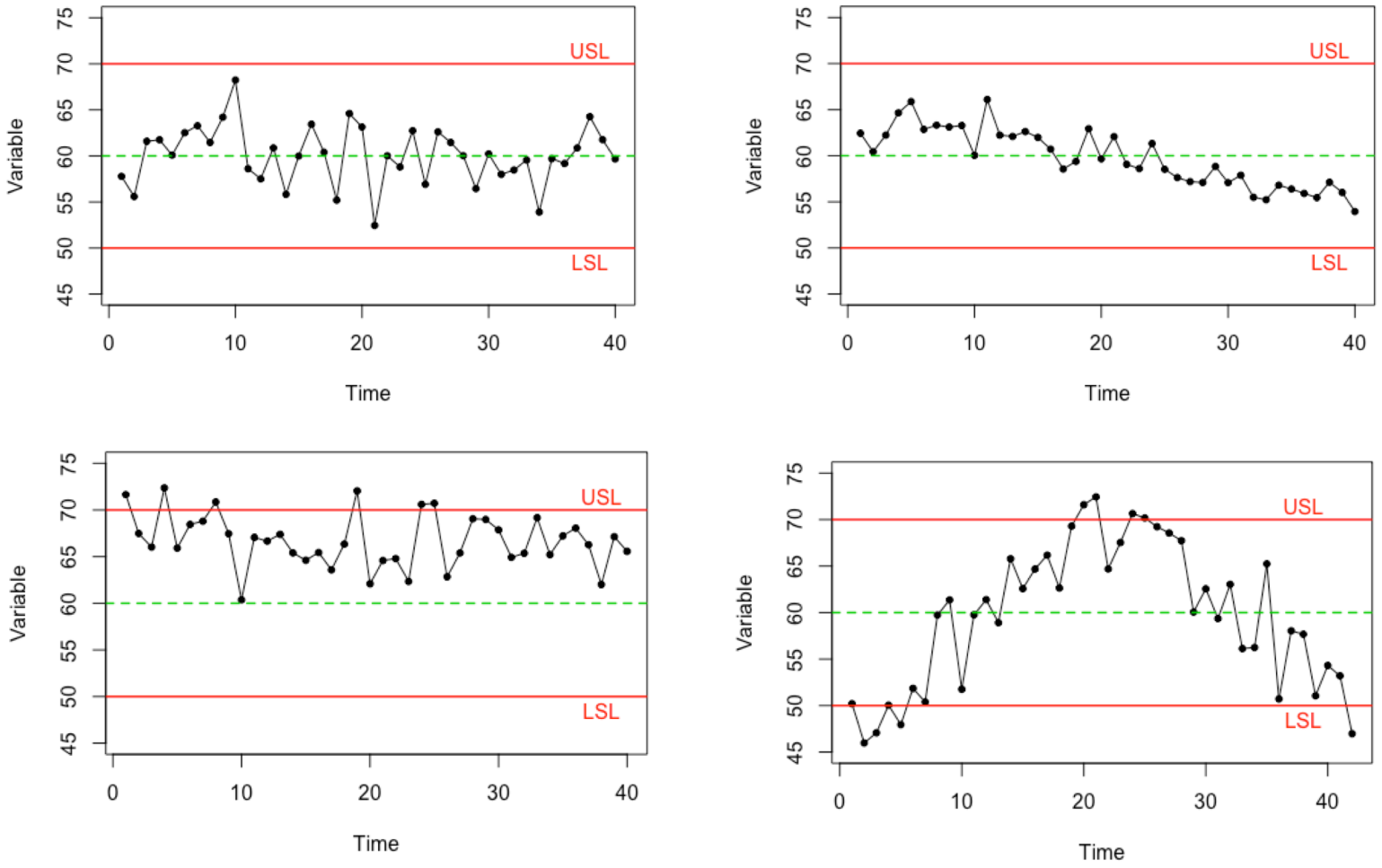






Tools for statistical process control
The basic concepts and vocabulary

4 processes – 4 different situations – what's the best ?



LSL = Lower specification limit

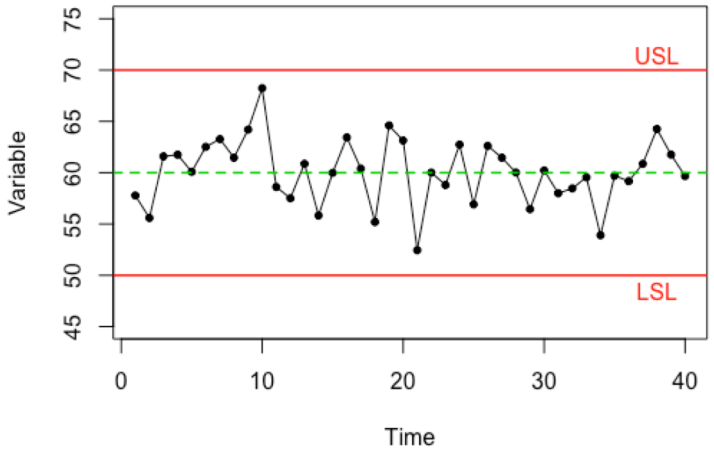
USL = Upper specification limit

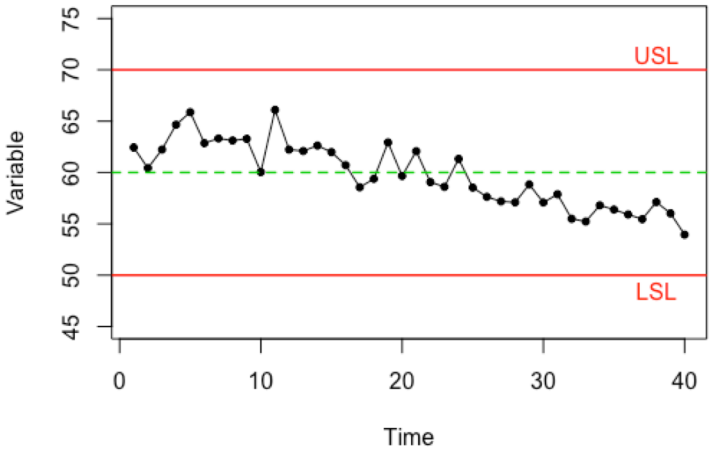
4 processes – 4 different situations – what's the best ?

Process under statistical control

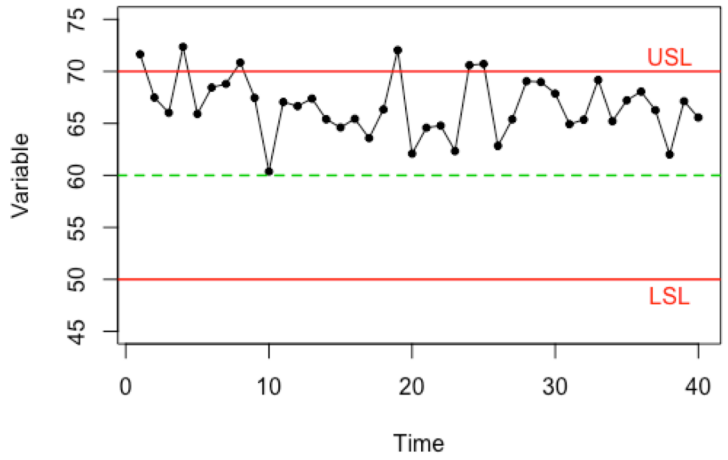
Process out of statistical control

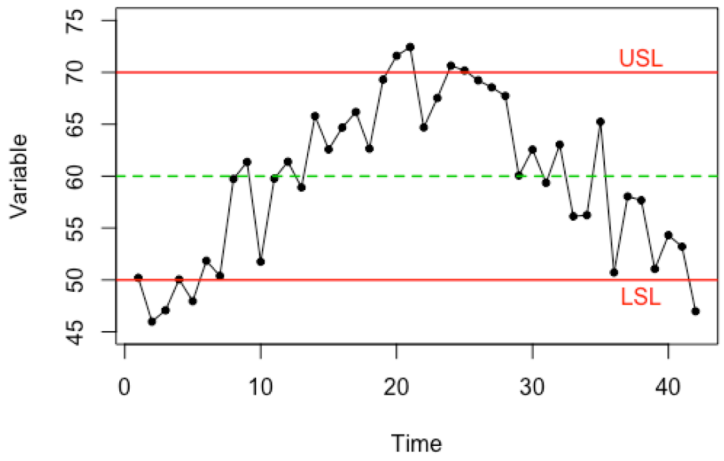
CAPABLE PROCESS





NON CAPABLE PROCESS





LSL = Lower specification limit

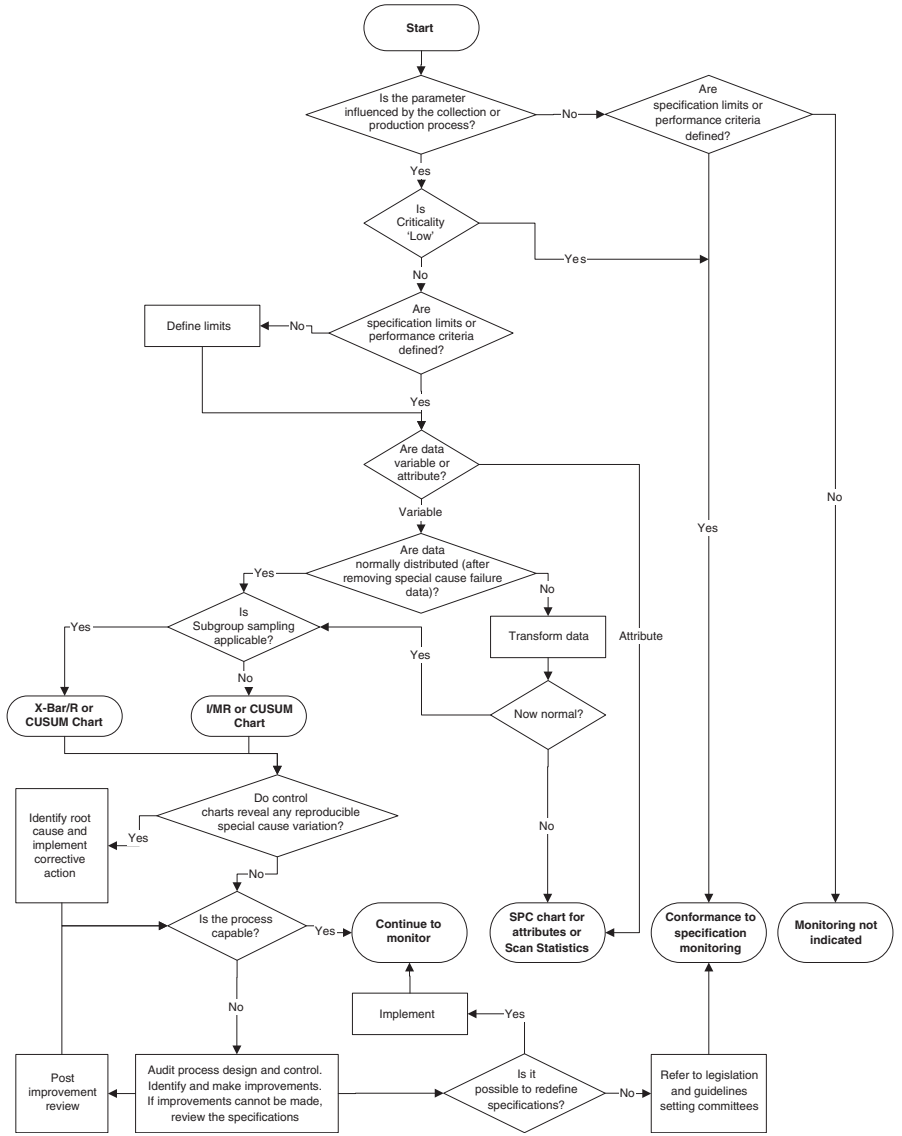
USL = Upper specification limit

Three questions: three classes of statistical quality control tools

Stability of the process over time	Control charts	X, Xbar-R, EWMA, p and Scan charts
Comparison of the production to the specifications	Capability analysis	% Non conform, Cpu, Cpl, Cpk
Conformity of a lot of material to the specifications	Acceptance sampling	Iso norms 2851 and 3951

Implementation of SQC by Beckman and all

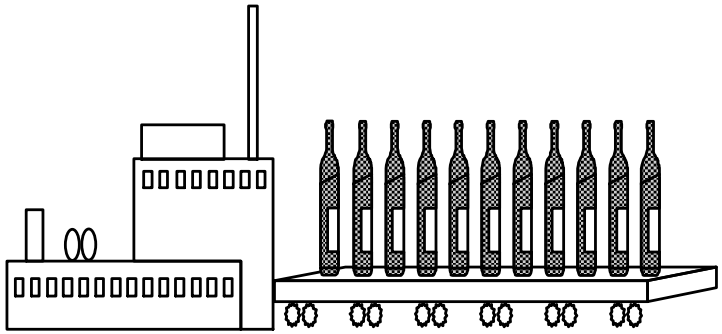
Statistical process control tools depend on the type of variables of interest and links between them.



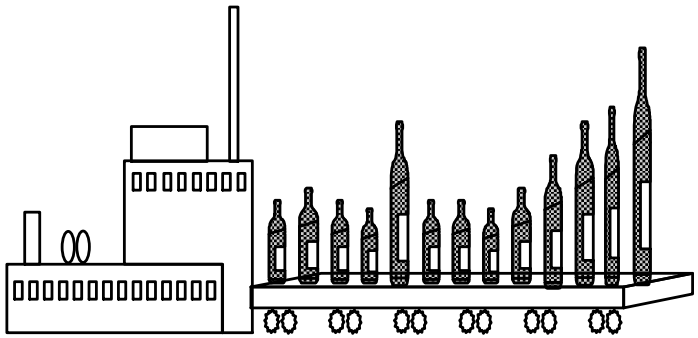
Control Charts
A tool to follow
the stability of a process over time

Control charts : motivation

This never happens – especially in blood treatment processes

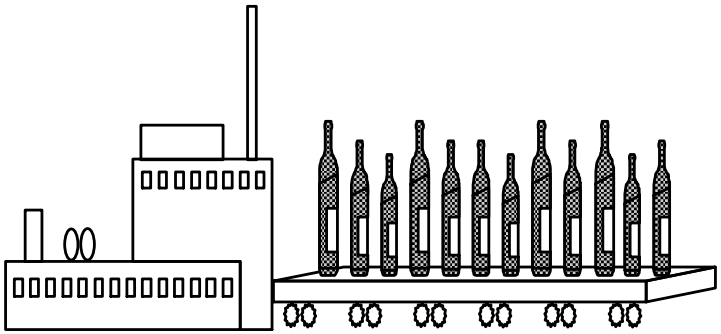


How can one make a difference between these 2 situations ?



« Special » causes of variation

Process out of statistical control



« Normal » causes of variation.

Process in statistical control.

Goal of control chart

Purpose

Verify if a production is stable over time

How ?

With a run chart

+ control limits

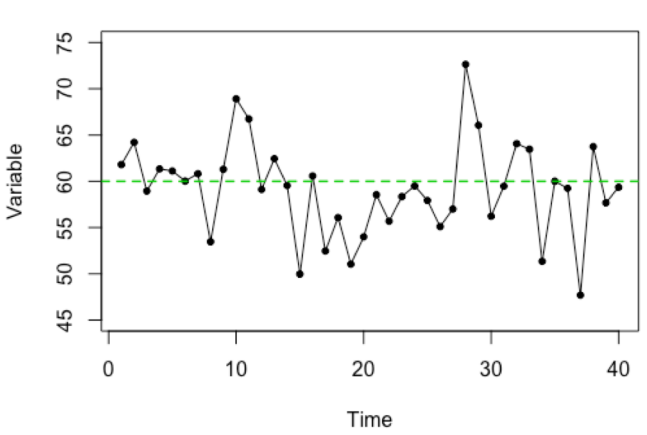
5 proposed charts

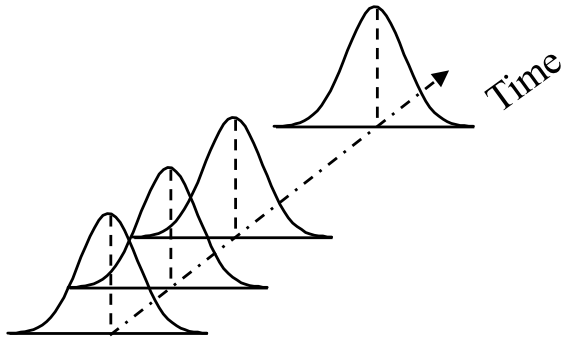
- X, Xbar-R
- Cusum and EWMA
- P and Scan

Hypotheses

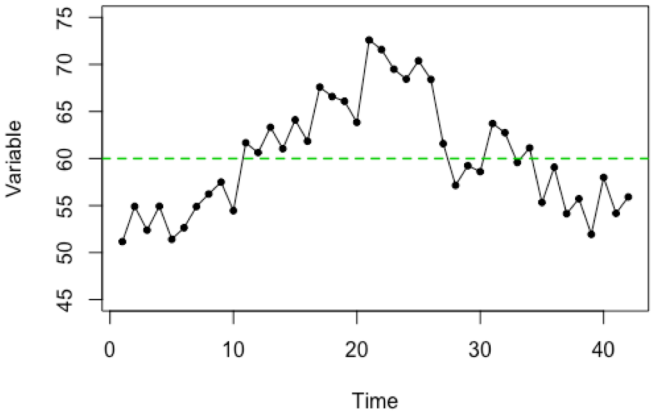
Normality of the data.
Transformation can help if not.

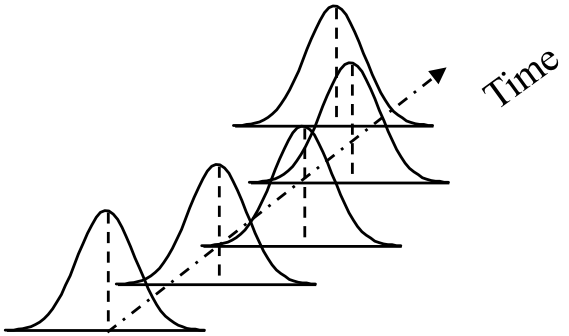
Process under statistical control



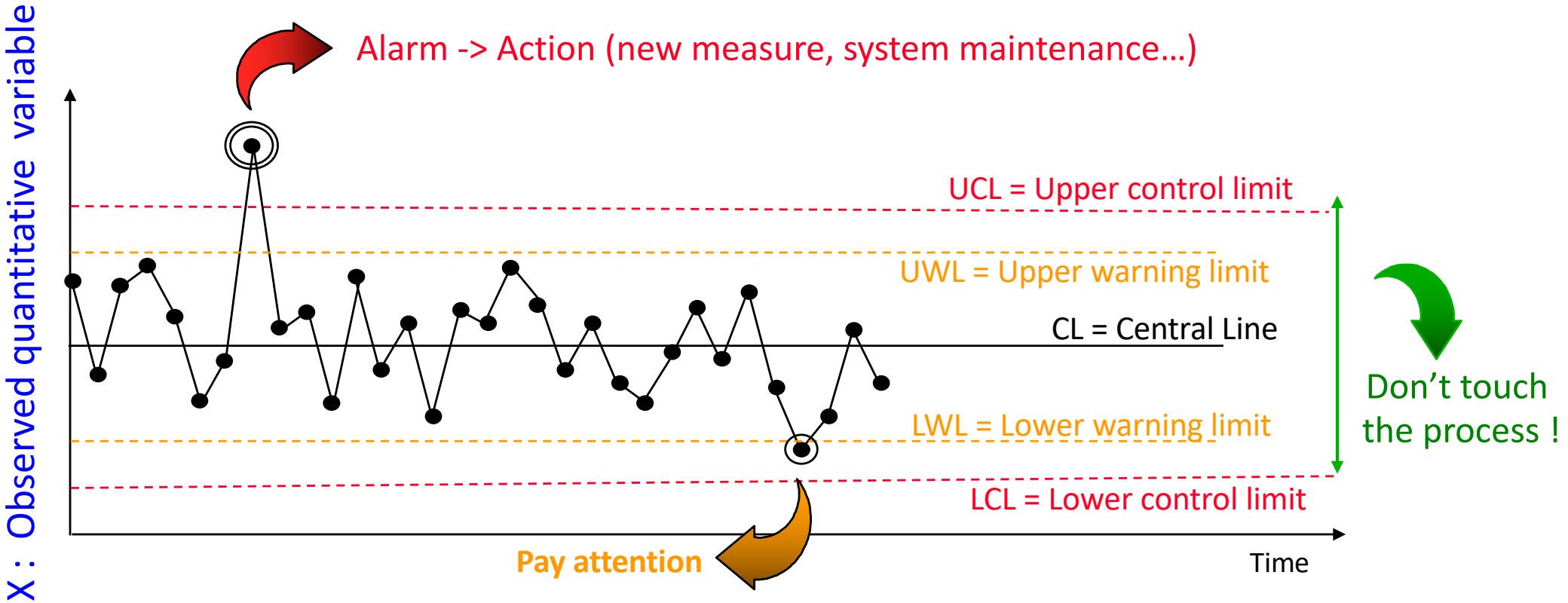


Process out of statistical control





Control chart definition and elements



Control chart = run chart + control limits (+ warning limits)

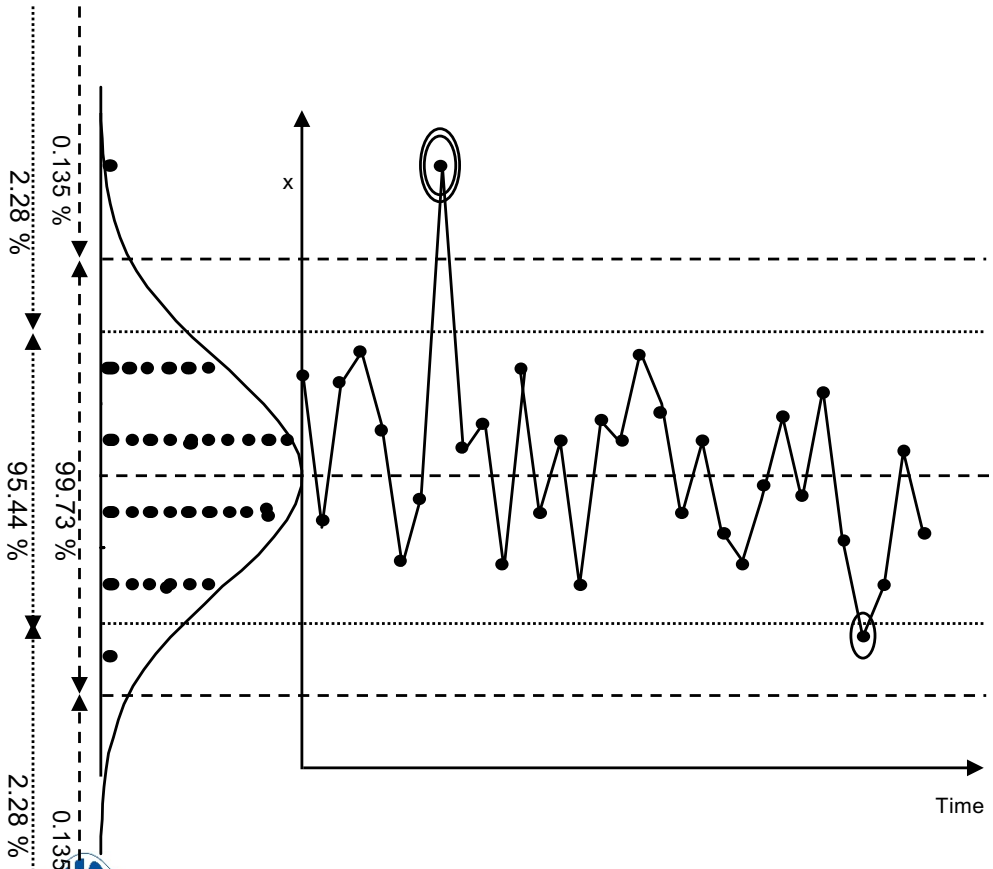
Control limits are NOT specification limits but statistical limits.

When the data point is in the limits → continue to produce

When the data point is out of control limits → Alarm, try to find the special cause

Choice of control chart limits

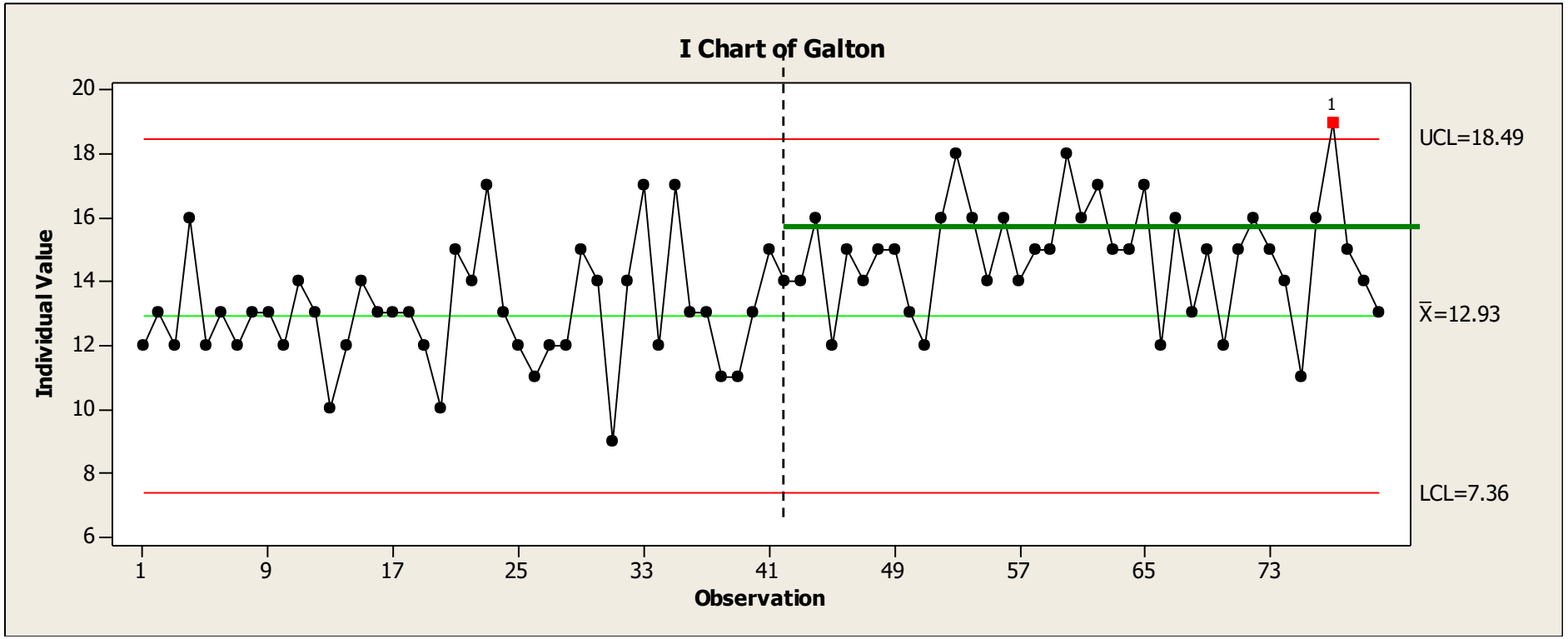
- If the process is under control and data are Normal,
  99.7% of the data should be in μ +/– 3σ and 95% in μ +/– 2σ .
- Control limits are usually set to μ +/– 3σ and warning limits at μ +/– 2σ .
- The limits are estimated on the basis of a reference data set under statistical control.



	Process parameters	Estimated parameters
UCL =	$\mu + 3\sigma$	$\bar{X} + 3\,S$
UWL =	$\mu + 2\sigma$	$\bar{X} + 2\,S$
CL =	μ	$\bar{X}$
LWL =	$\mu - 2\sigma$	$\bar{X} - 2\,S$
LCL =	$\mu - 3\sigma$	$\bar{X} - 3\,S$

Example : the « Galton » data

- 80 data points generated from the Galton table.
- $\mu = 13$ for n = 1 to 40 and $\mu = 15$ for n = 41 to 80 and $\sigma = 2$.
- Limits are calculated on the first 40 data points.

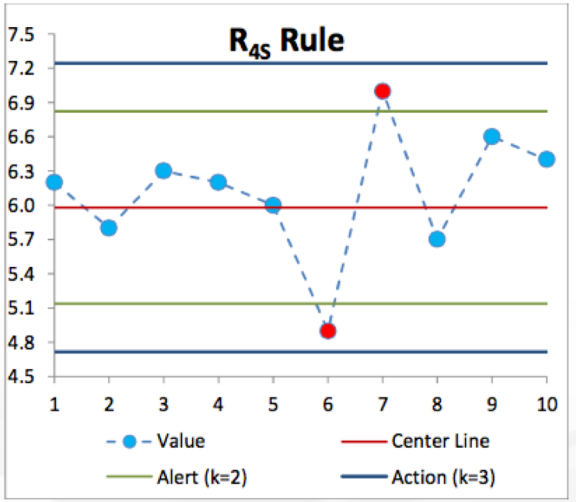


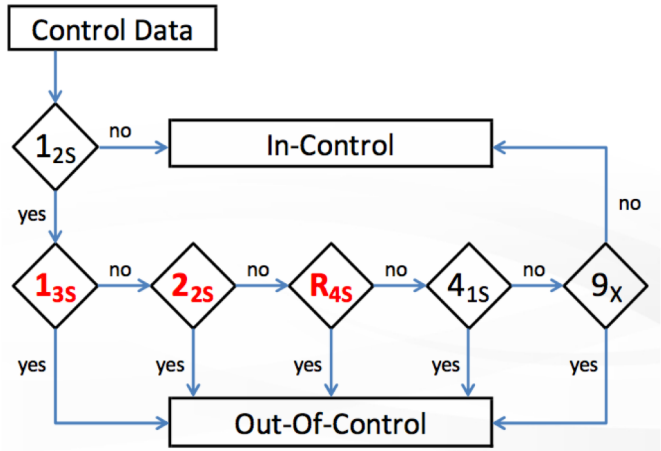
The first alarm appears only at point 77.

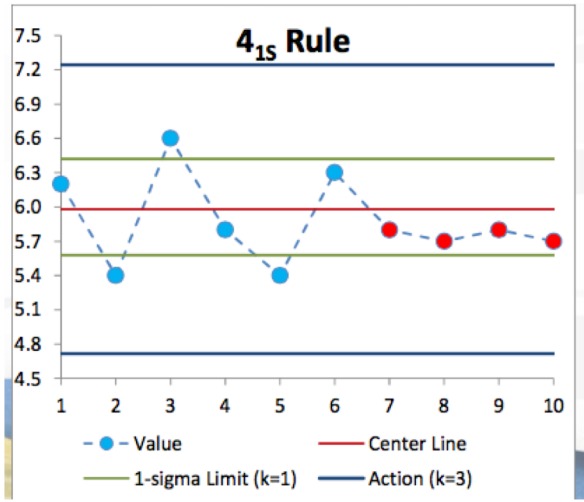
X-chart is not very reactive when the mean shift is small

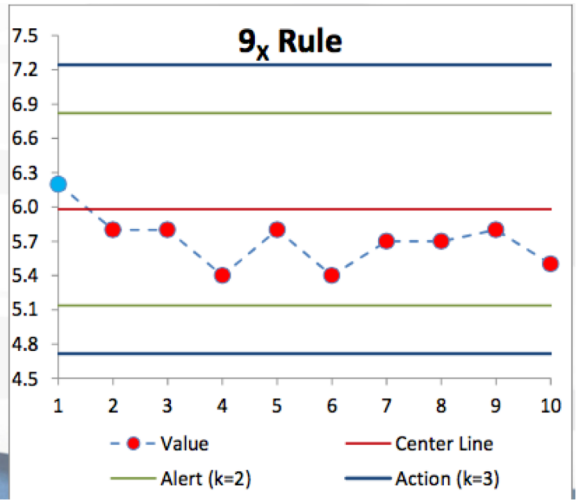
Westgard' Rules

Westgard control rules help to increase the reactivity/sensitivity of control charts





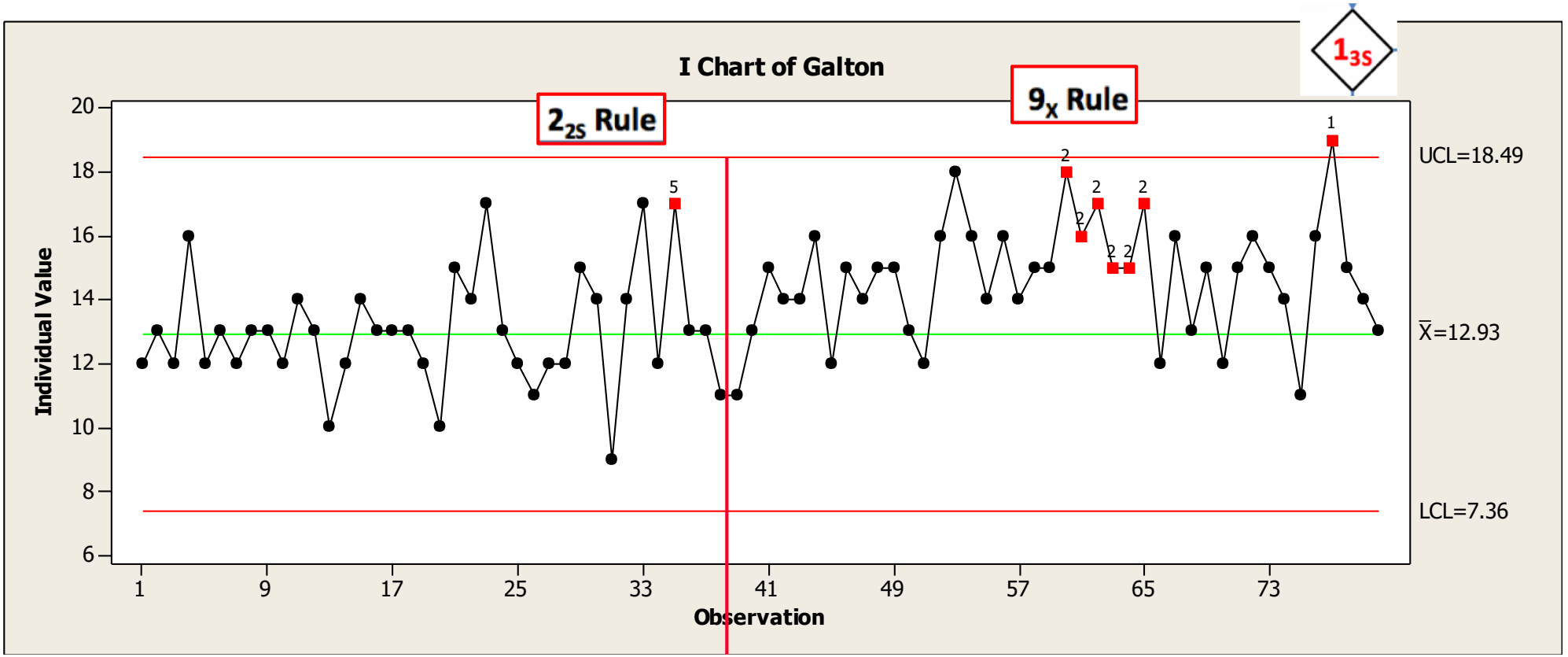




Rule	Most Probable Root-Cause	
	Random Error	Systematic Error
Warning	1_{2S}	4_{1S}, 9_X
Rejection	1_{3S}, R_{4S}	2_{2S}

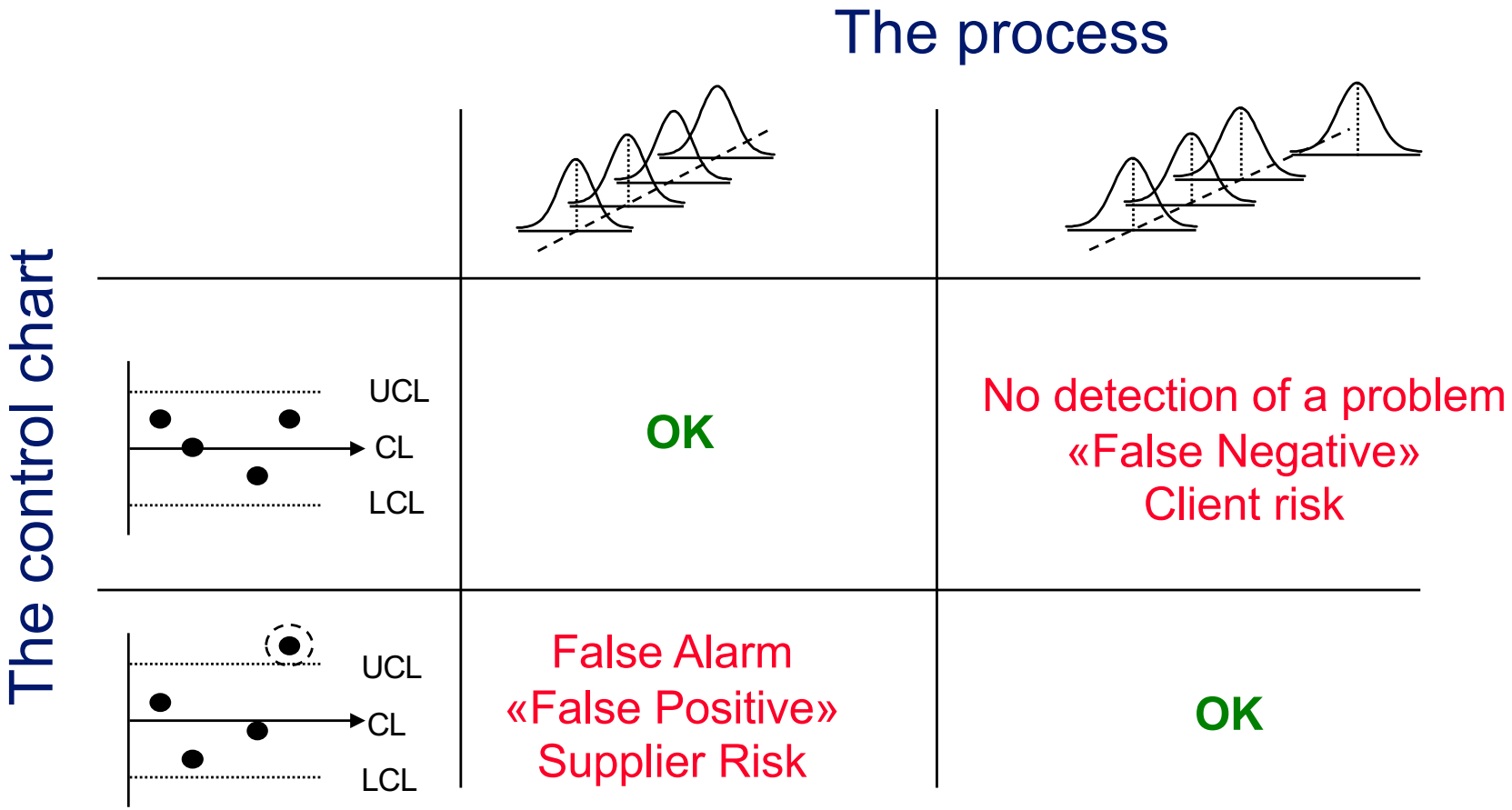
Extracted from D. Le Tallec B-QM Conference - Oct 17

Example – galton data (2)



With Westgard rules, a first alarm appears at point 60
but a false alarm appears at point 34 !

A control chart can take the wrong decision



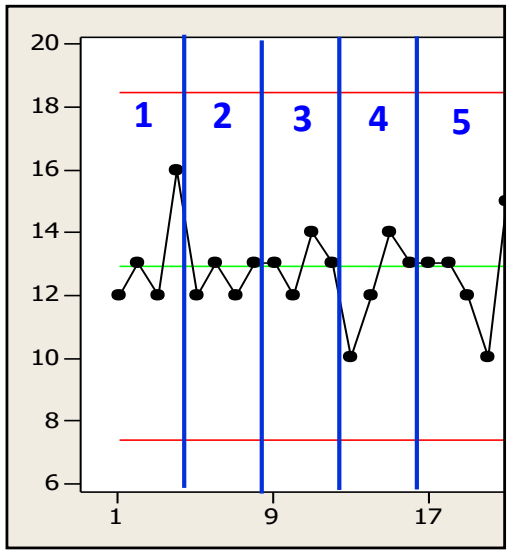
The control chart and the sampling should be chosen to minimize false positive and false negative rates.

Some classes of control charts are more efficient than others !

Mean and Range chart or Xbar-Range chart

Principle of Xbar-Range chart

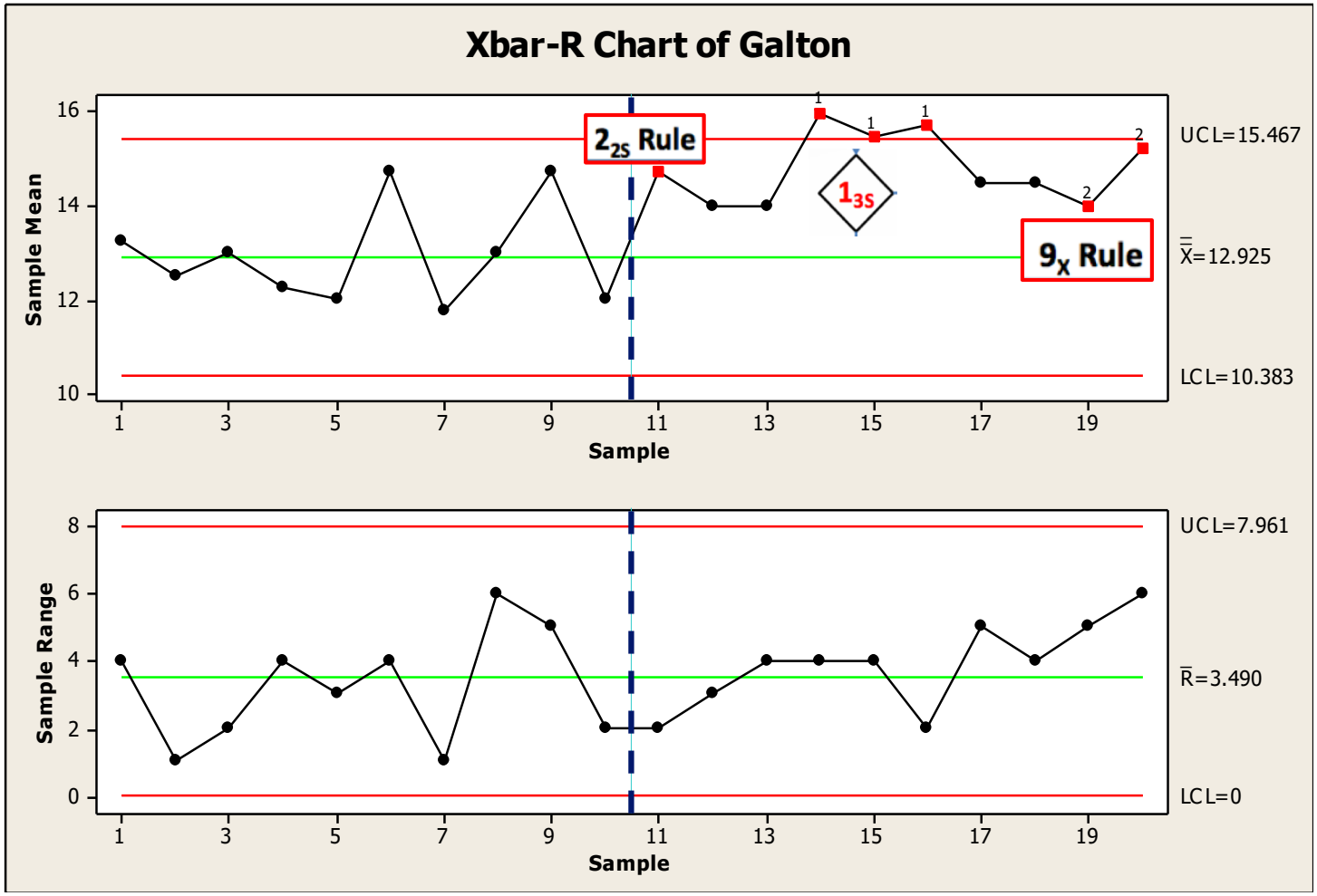
- Group the data by sub-groups of size n (e.g. n=4)
- Represent the group means on one chart to follow the « position » of the process
- Represent the group ranges on a second chart to follow the « dispersion » of the process



Group	Data	Mean - Xbar	Range
1	12 13 12 16	13.25	4
2	12 13 12 13	12.5	1
3	13 12 14 13	13	2
4	10 12 14 13	12.25	4
5	13 13 12 10	12	3

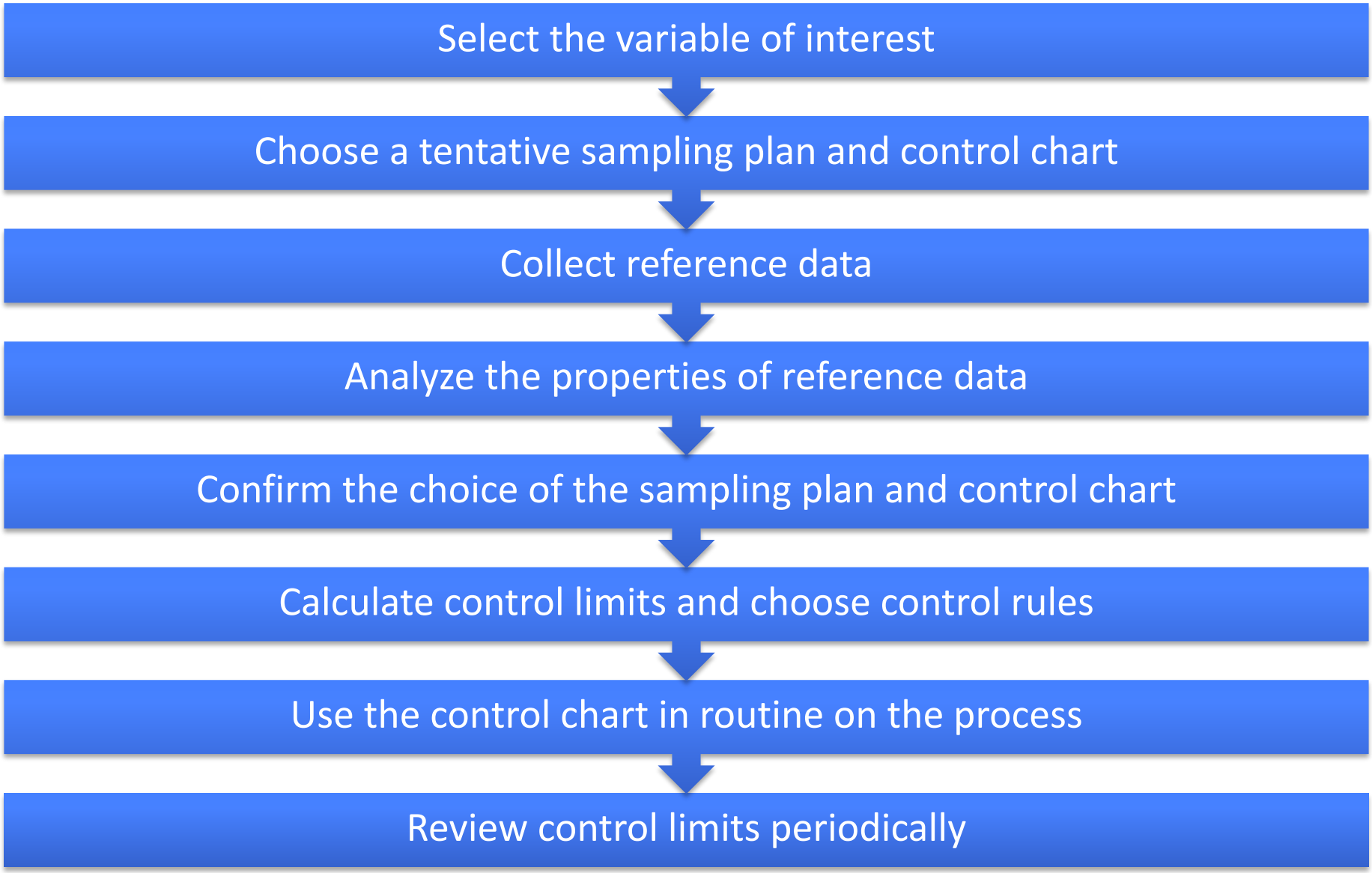
Example – Galton data (3)

Xbar-R chart on Galton data



With the Xbar-R chart a first alarm appears just after the mean shift.

Steps to set up a control chart



Example of chart set up (1)

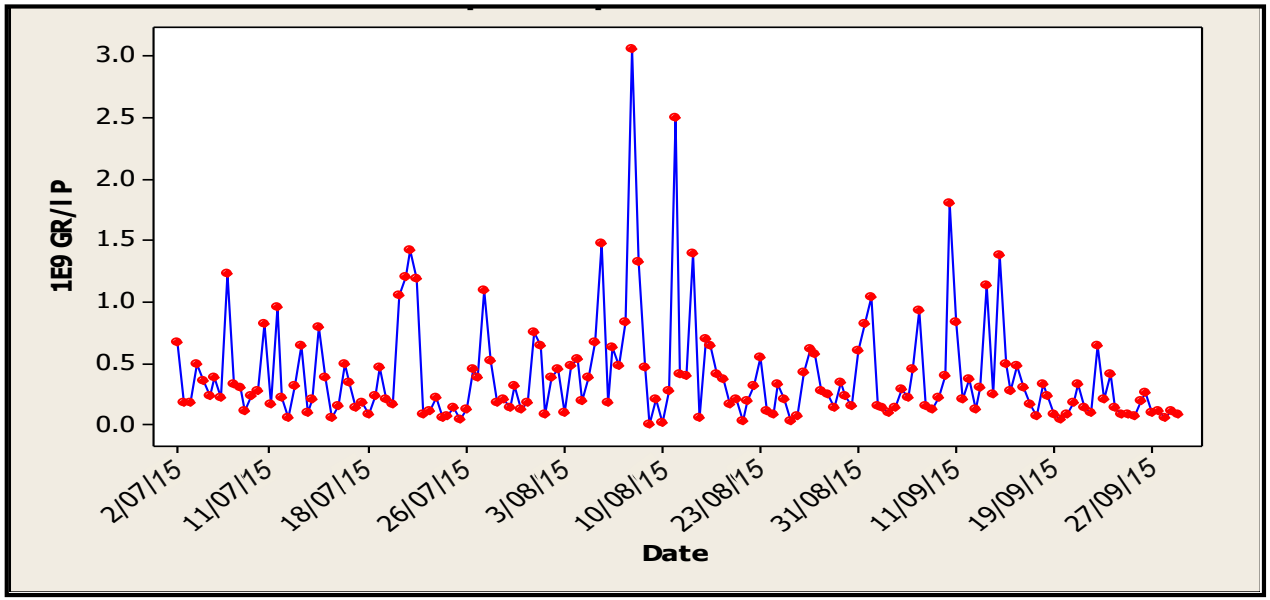
Select the variable of interest

Red cells in plasma (1E9/L)

Choose a tentative sampling plan and a control chart

- 3 bags a day on one centrifuge and two separators
  - → The number of samples must be chosen to balance cost and sensitivity/reactivity of the chart
  - → The sampled units must be representative of the whole process
- Mean and range chart
  - → Data are summarized by day on the chart (one point corresponds to one day).

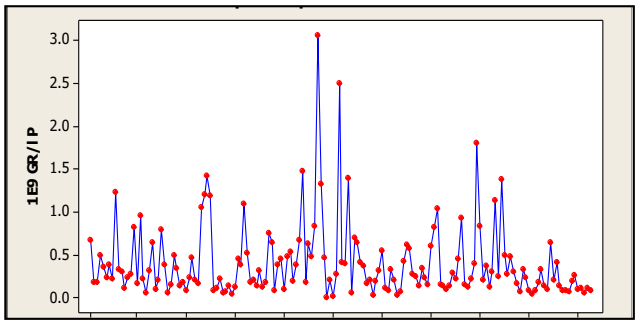
Collect reference data during 3 months

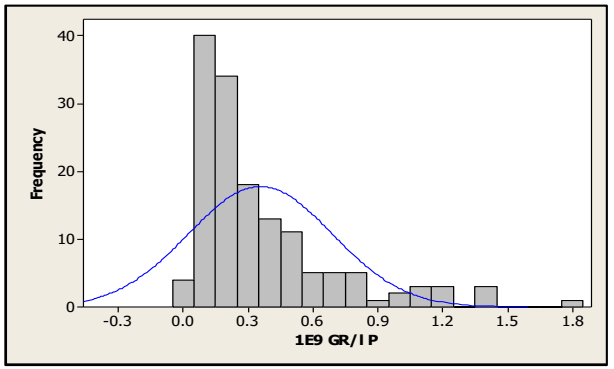


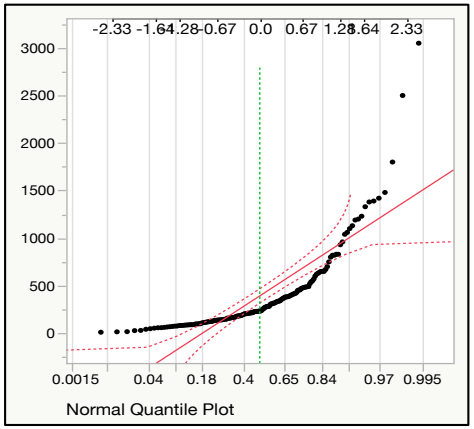
Example of chart set up (2)

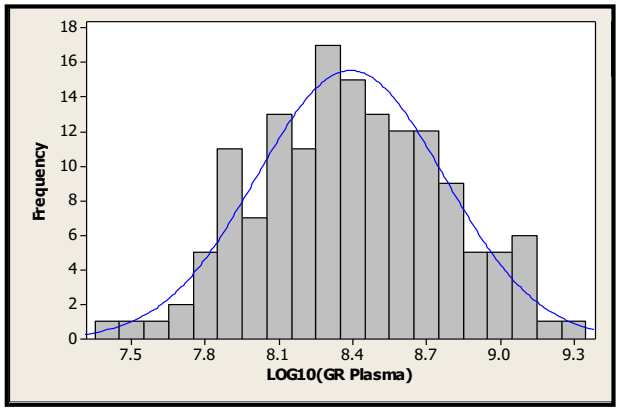
Analyze the properties of the data

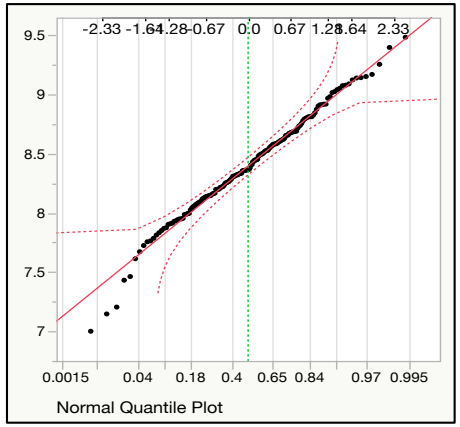
- Data are not normally distributed but a logarithm transformation solves the problem

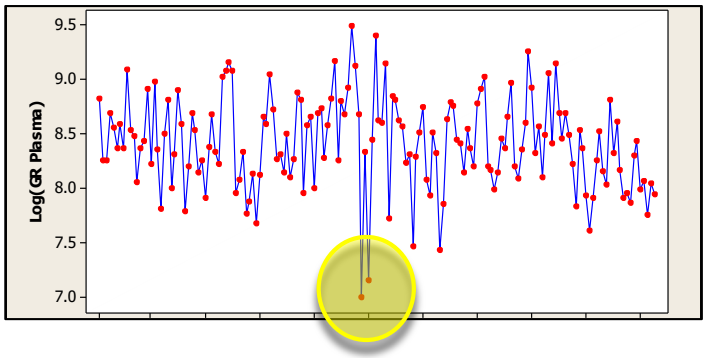










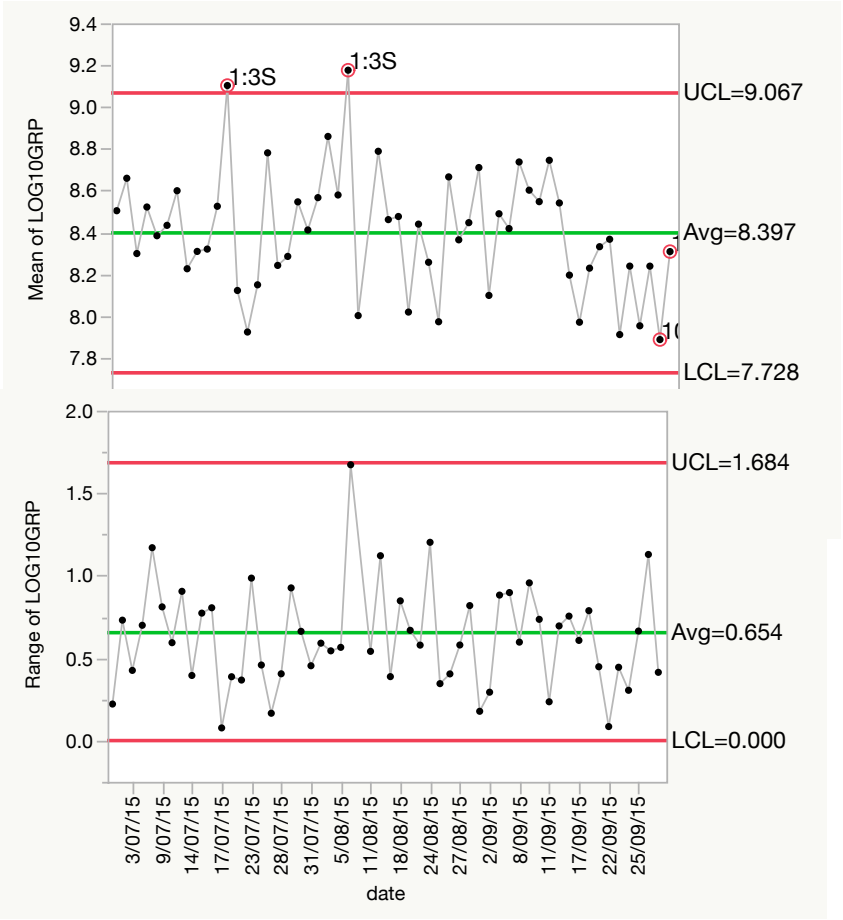


- Other properties must be verified : independency and presence of outliers.
- Remove important outliers and unstable periods to calculate the control limits.

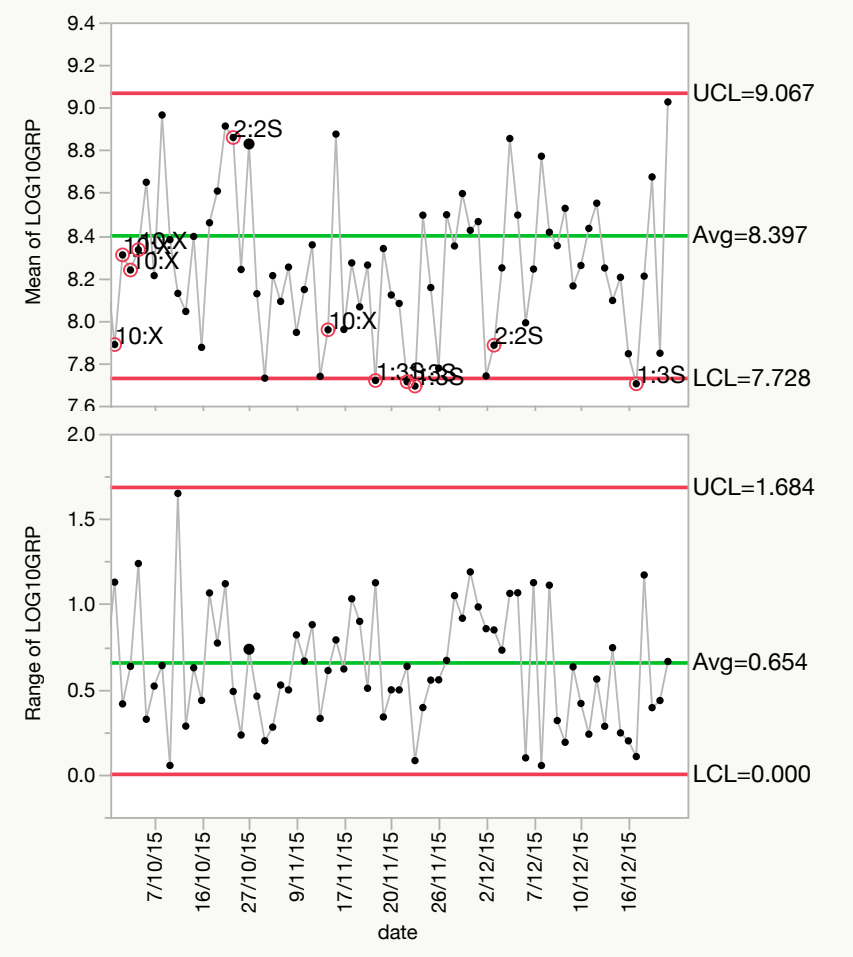
Example of chart set up (3)

Calculate control limits and then choose control rules

(WR : 1-3S, 2-2S, 10X)



Use the control chart in routine on the process

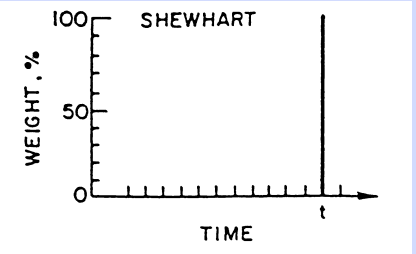
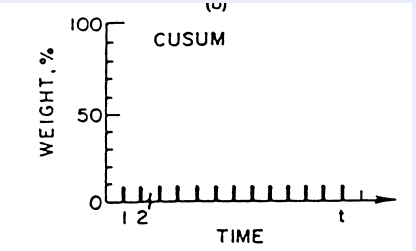
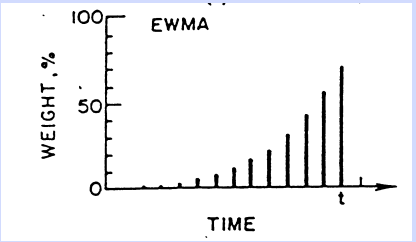


Annual QC system update

Fichier	variable	distribution	calcul limites contrôles	données calcul limites contrôle	nb données	Mu/ pbar	Sigma	k	Ligne centrale	taille groupes	UCL	LCL	Remarques
CQ_CED_PEDI_2016	pas de CQ												
CQ_CED_Plasma_2016	Vol ST												Impossible à ajuster (trimodale)
	Hb/unite	normale	mu+k*sigma	Toutes les données sauf la plus petite et la plus grande	1187	49.52	6.158	3	49.520	6	57.062	41.978	
	Récupération Hb	normale	mu+k*sigma	Toutes les données sauf les quatre plus petites	1048	0.7506	0.03297	3	0.751	6	0.791	0.710	
	1E9 GR Plasma	lognormale	exp(mu+k*sigma)										nouvelle méthode de comptage donc pas de limites
	Hb (mgr/L)	lognormale censurée à gauche	exp(mu+k*sigma)		1028								impossible à ajuster car 843 mesures valent 17 (la censure) sur 1028
CQ_LG_CUPminicup_2016	GR/µl												262 observations sur 526 valent 0 donc impossible à estimer
	Conc plaq(ml) av PRT - D (colonne C34)	lognormale	exp(mu + k*sigma)										Impossible à ajuster (cf. histogramme dans feuille histogrammes du fichier excel)
	Conc plaq(ml) av PRT - S (colonne C34)	lognormale	exp(mu+k*sigma)	Toutes les données sauf les trois plus grandes	372	21	0.150	3	1.32E+09	2	1.81E+09	9.60E+08	
	Récup Plaq	normale	(recup)	Toutes les données inférieures à 100 % sauf les trois plus petites	493	0.907	0.032	3	90.65%	3	96.12%	85.18%	
	Conc plaq(ml) ap PRT (colonne C40)	lognormale	exp(mu + k*sigma)	Toutes les données sauf les 7 plus petites et les 6 plus grandes	500	20.95	0.141	3	1.25E+09	3	1.60E+09	9.82E+08	
CQ_Hémolyse_2016	%hemolyse	lognormale	exp(mu + k*sigma)	Toutes les données	100	-1.433	0.396	3	0.239	2	0.552	0.103	
CQ_P_Aph_2016	Hb (mgr/L)	lognormale censurée à gauche			714			3		5			598 sur 942 observations sont censurées donc impossible à estimer
	GR												nouvelle méthode de comptage donc pas de limites
CQ_pH_2016	pH CUP	normale	Mu + k*sigma	Tout sauf les deux plus petites	29	6.905	0.114	3	6.905	2	7.147	6.663	
	pH Pool	normale	Mu + k*sigma	Toutes les données	69	6.956	0.081	3	6.956	2	7.129	6.783	
CQ_Plasma_VI_2016 Cell Résid	protéines totales	(PT) suit une normale censurée par intervalle	(Mu + k*sigma)	Données sauf la plus petite	171	57.09	3.15	3	57.090	1	66.540	47.640	
CQ_Plasma_VI_2016 Fc VIII	%recover	'(FcVIII)^3 normale	(mu+k*sigma)^(1/3)	Toutes les données sauf celles au-dessus de 100 % et les deux plus petites	129	0.702	0.163	3	0.889	1	1.060	0.597	Pour les poches ST. UCL ramenée à 1
CQ_Pool_PRT_2016	Nbr Pl Pool avt E (C23)	Normale	mu + k*sigma	Toutes les données sauf la plus petite et les quatre plus grandes	345	4.388	0.566	3	4.388	2	5.589	3.187	en 1E11
	Nbr Pl PRT (C28)	Normale	mu + k*sigma	Toutes les données sauf les 10 plus petites et les 4 plus grandes	337	4.065	0.475	3	4.065	2	5.073	3.057	en 1E11
	CC Pl/ml PRT (C29)	Normale	(Mu + k*sigma)	Données à partir du 1er juillet	155	1.346	0.186	3	1.346	2	1.741	0.951	en 1E9 Il y a une tendance à la hausse sur l'ensemble de l'année, c'est pourquoi j'ai commencé seulement au 1er juillet pour obtenir quelque chose de plus constant.
	GR/µl												71 observations sur 157 valent 1 donc impossible à ajuster
CQ_RATIO_PAS_2016	%PAS	normale	(mu+k*sigma)	Toutes les données à partir du 1er juillet sauf les 2 plus petites et la plus grande	301	0.6498	0.01161	3	0.650	4	0.667	0.632	pour les trima
CQ_BC_2016	Vol BC	normale	(mu+k*sigma)	Toutes les données sauf les deux plus petites et la plus grande	2502	44.435	2.242	3	44.435	15	46.172	42.698	limites pas utilisées car changement séparateur (je les ai laissées dans la macro mensuelle)
	Hc BC	lognormale	exp(mu + k*sigma)	Toutes les données sauf les 7 plus grandes et les 3 plus petites	2495	3.6808	0.112	3	39.68	15	43.27	36.38	limites pas utilisées car changement séparateur (je les ai laissées dans la macro mensuelle)

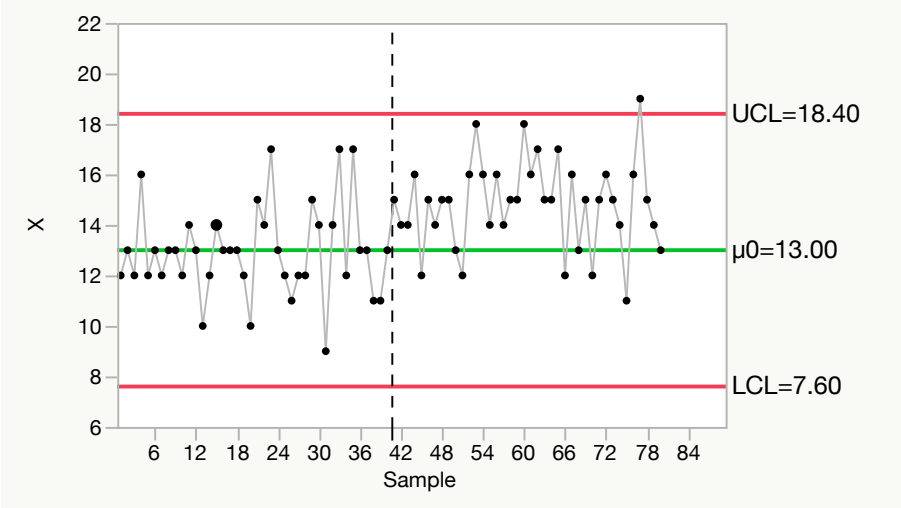
CUSUM and EWMA charts: a cheap way to find a small shift.

- X-charts are only sensible to big mean μ shifts
- Xbar-R charts are more sensible but also more expensive
- CUSUM and EWMA charts allow to detect small shifts at low cost.

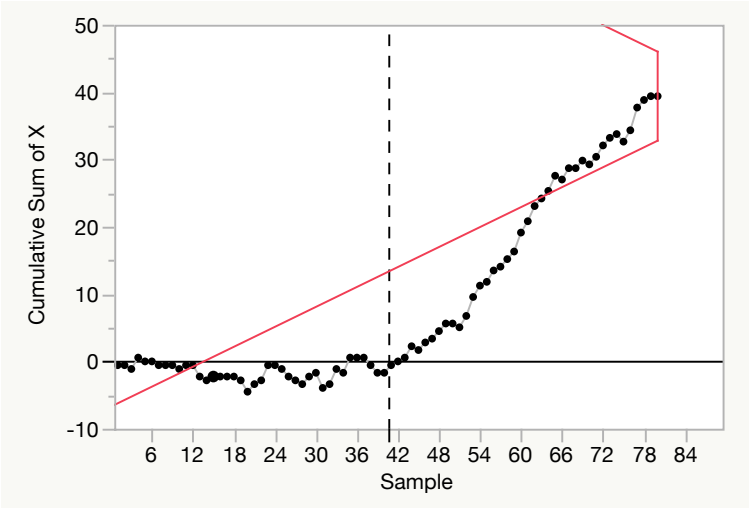
Chart	What is represented ?	
X	The observation at time t : X_t	
CUSUM	The cumulative sum of the difference between the observation and the target value τ. $S_i = \sum_{j=1}^{i}(X_j - \tau)$	
EWMA	A weighted moving average of current and past observations. $Z_i = \lambda X_i + (1-\lambda)Z_{i-1}$	

CUSUM and EWMA charts on the Galton data

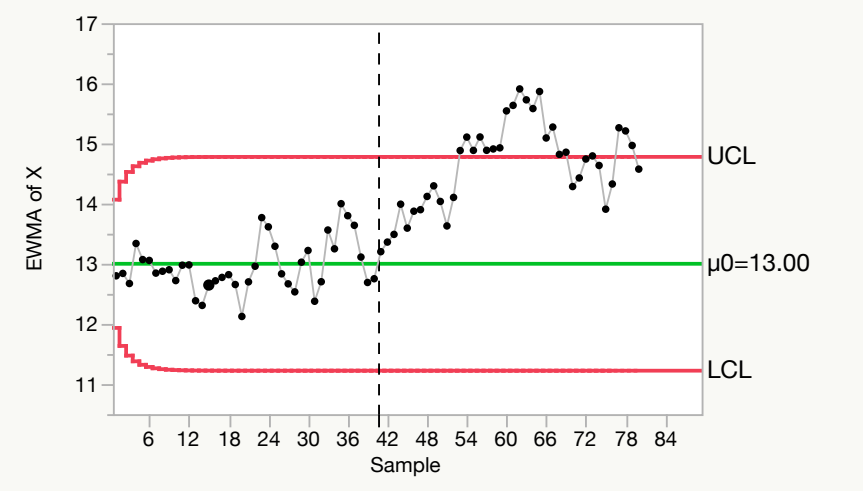
X Chart



CUSUM Chart



EWMA Chart



Control charts for attribute data. When and what ?

Attribute data

→ Anything that is counted on a “Yes” / “No” basis

→ Visual inspection, test of conformity or not …

When ?

→ When no quantitative measure is available

→ When quantitative data are not Normal data (even after transformation)

→ When the conformity is more important that the data itself

What ?

→ Attribute control charts are more used than “measures” control chart

→ BUT they are less efficient !

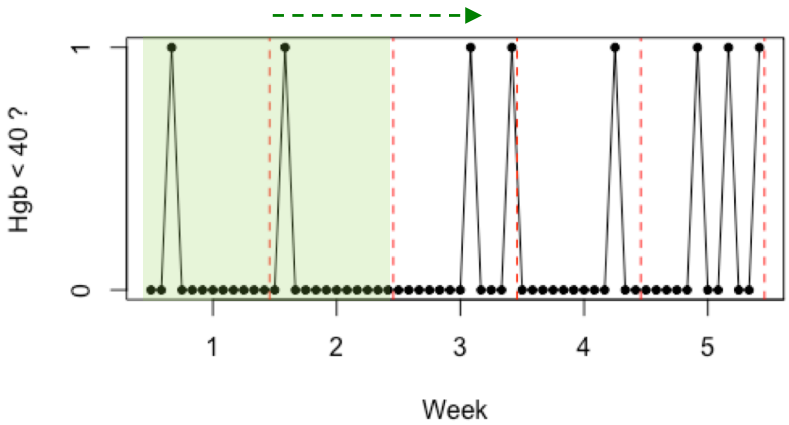
→ Most used attribute control charts in blood transformation processes :

p or np charts and Scan statistics

P charts and scan statistics

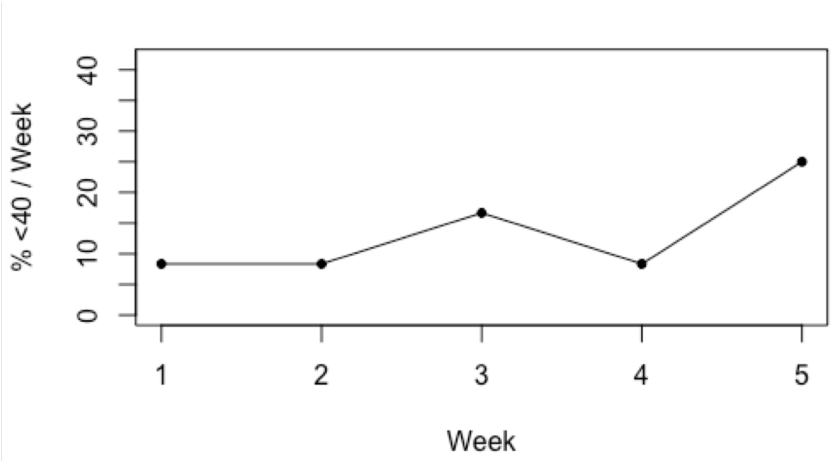
Example

- Hgb by unit RBC transformed into conformed and non conformed
- Y = 1 if Hgb < 40 and Y = 0 when Hgb ≥ 40
- Variable of interest : % out of spec per week



P-Chart

Each week : one point on the chart = % out of spec

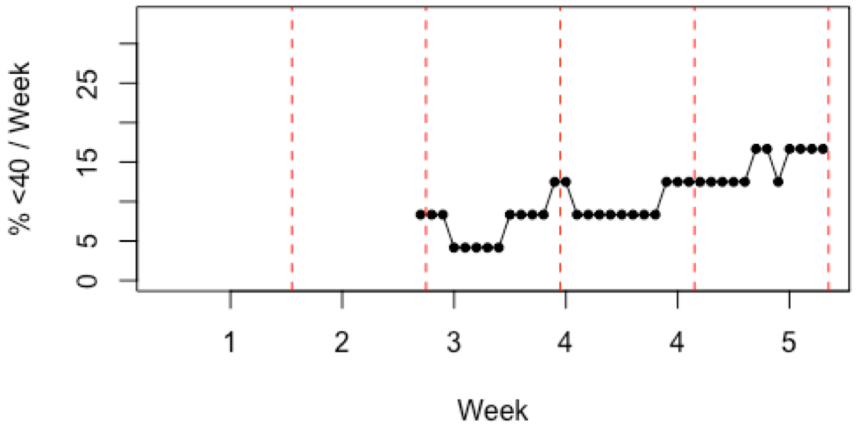


Scan Statistic

A window is chosen and moved point by point.

For each point the % out of spec is reviewed.

Example : 2 weeks window



Control limits on p and scan charts

Principle of control limits calculation

- Binomial distribution is usually used to calculate the limits
- Choosing control limit to get given false negative and positive rates is difficult.
- Tables or performance curves are provided.
- Hypergeometric distribution based charts are less expensive when the number of items produced is not high (because binomial hypothesis of sampling in an “infinite population” is incorrect)

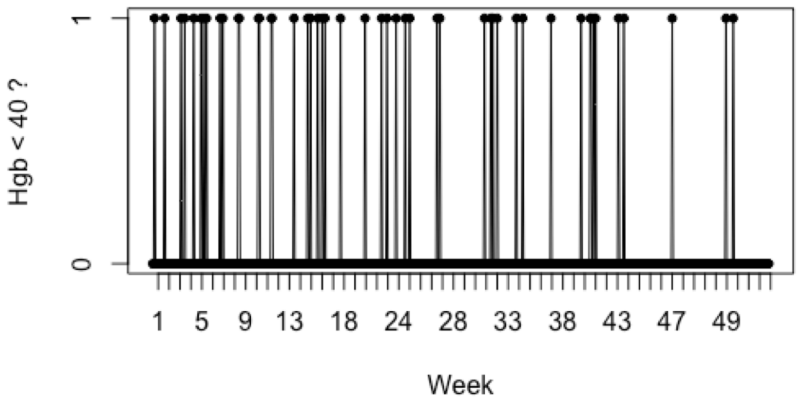
Table 1. Sample size (‘window’) and maximum number of failed tests allowed for a conforming process based on scan statistics

Allowed failure rate for a con-forming process	Number of tests in ‘universe’ (e.g. the number of tests per year)	Sample size (i.e. the fixed number of tests in a moving ‘win-dow’)	Maxi-mum allowed number of failed tests in window	False pos-itive rate of test criterion	Minimum failure rate of a non-conforming process detectable at > 80% power in any single ‘window’	
					Minimum ‘target fail-ure rate’ for a non-con-forming process	Power to detect non-conforming process in any window of quality control tests
25%	400	30	16	2.5%	63%	81.9%
		60	26	2.9%	50%	81.7%
	1 200	30	17	2.0%	66%	81.3%
		60	27	3.8%	52%	83.0%
10%	400	30	9	3.5%	40%	82.4%
		60	14	2.7%	30%	83.8%
	1 200	30	10	2.8%	43%	81.1%
5%	400	30	6	3.7%	29%	81.0%
		60	9	2.3%	21%	83.7%
	1 200	30	7	2.2%	33%	82.3%

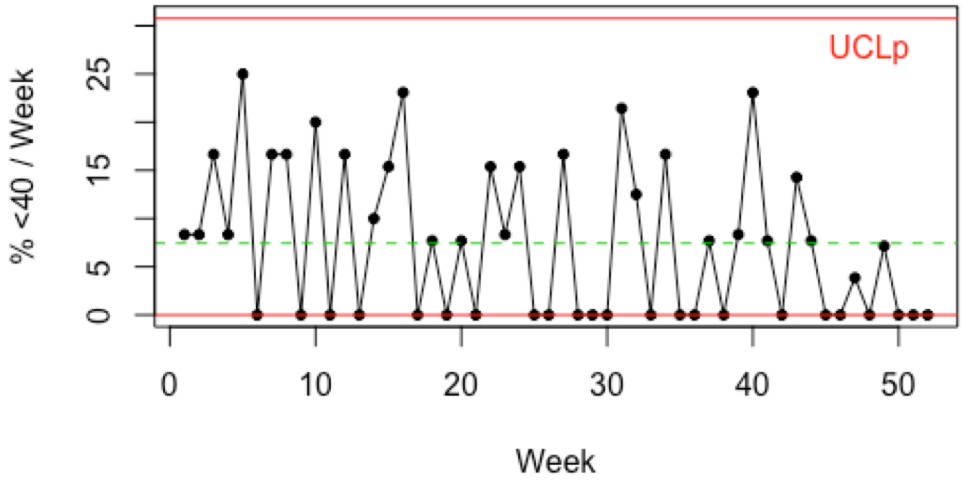
EDQM guide

P chart and scan statistics chart on Hgb <40

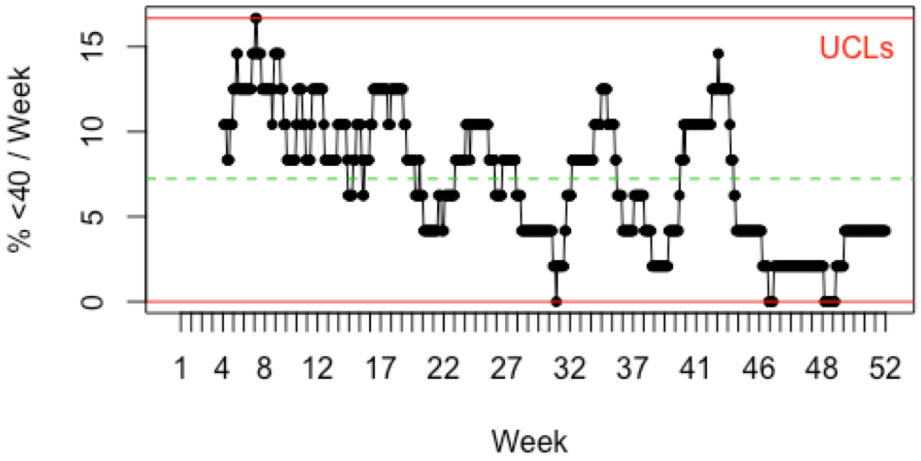
Individual values



P – Chart per week



Scan statistics
Chart with 4 weeks window

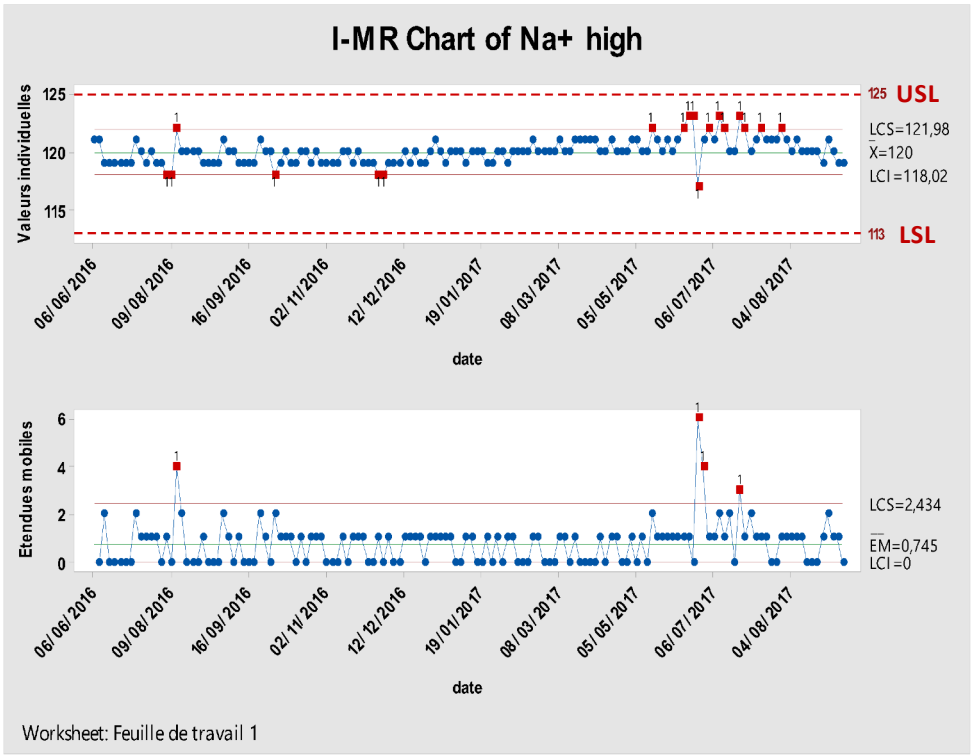


The choice of the window in the scan statistics works as the lambda in EWMA charts
It allows to see small shifts and long term tendencies.

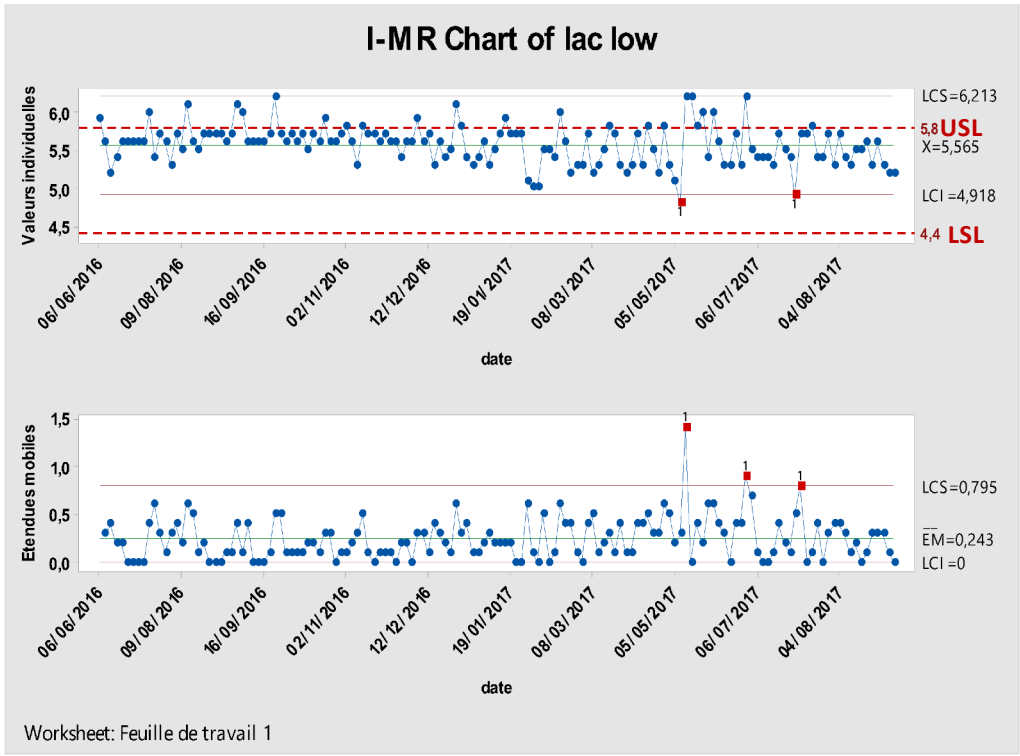
Control chart in the analytical laboratory

Control charts are also commonly used on the analytical lab to check daily the stability of control samples. A control chart system is often provided with the measurement device.

Example : GEM - blood gas analyzer



Sodium



Lactate

Capability indices to compare the state of the production to the specifications

Goal of capability analysis

Purpose

Verify if a production is well inside the specification limits LSL and USL of the variable of interest.

How ?

By the use of an objective "capability index" that does not depend on the units of the variable and specs.

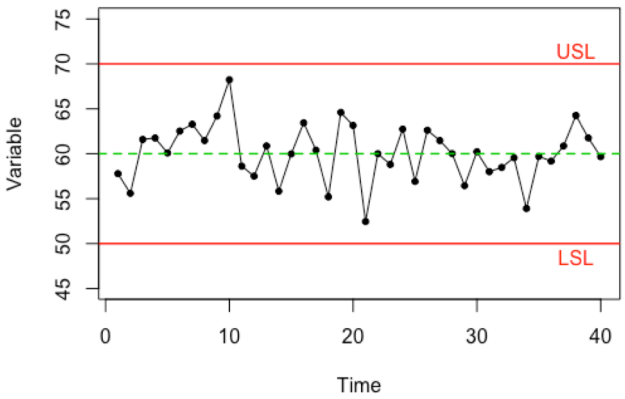
2 indices proposed

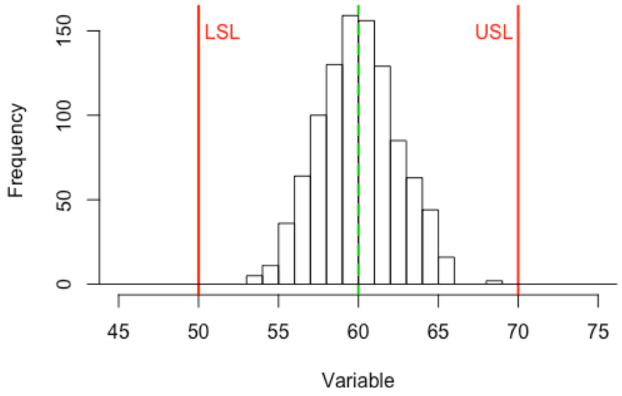
- % out of specification
- CPK

Hypotheses

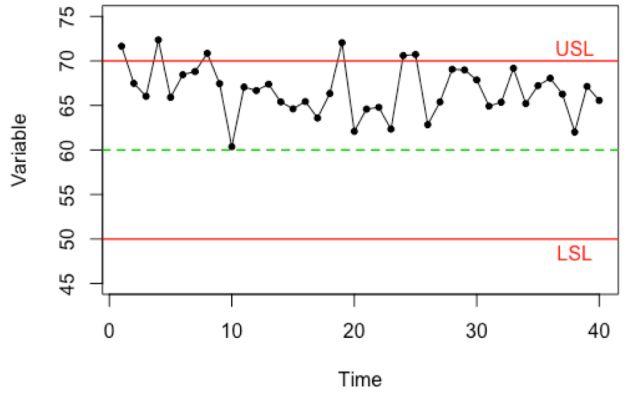
Normality of the data but adapted criteria exist for non normal data.

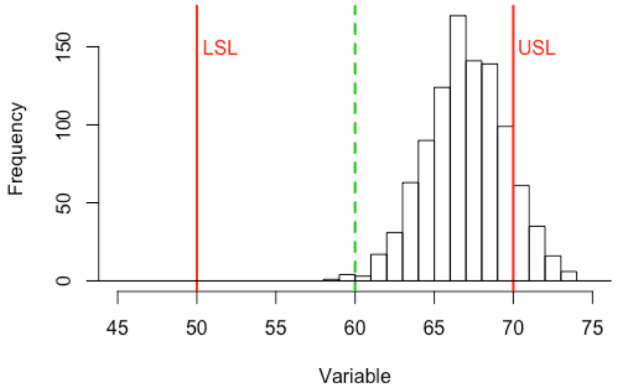
CAPABLE PROCESS





NON CAPABLE PROCESS



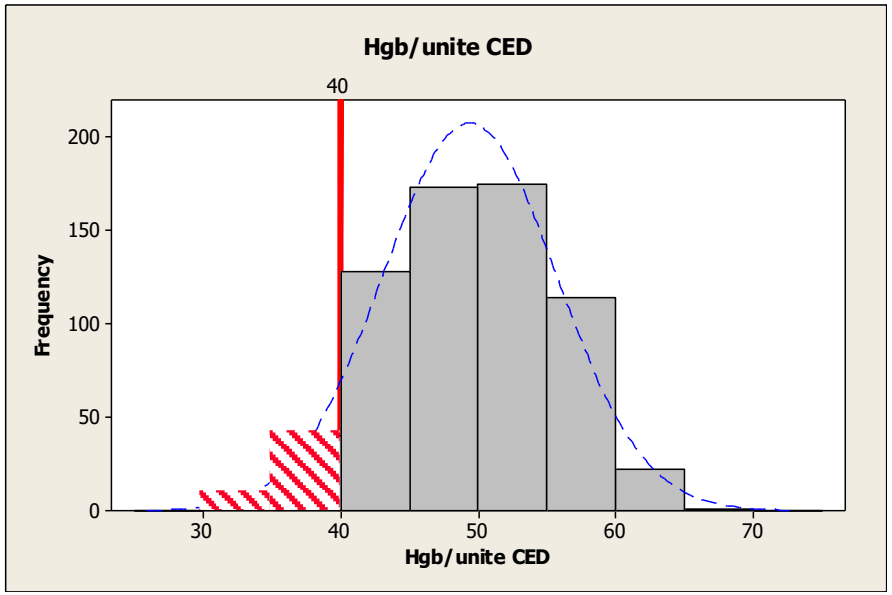


LSL : Lower specification limit USL = Upper specification limit

Observed or estimated out of spec proportion

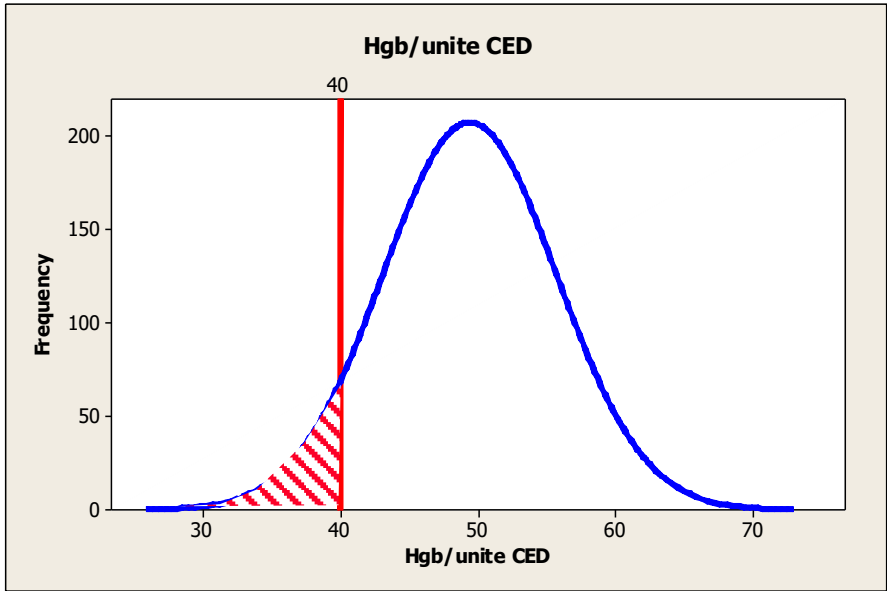
- Observed out of spec proportion

  Percentage of observations that are out of the specifications limits.



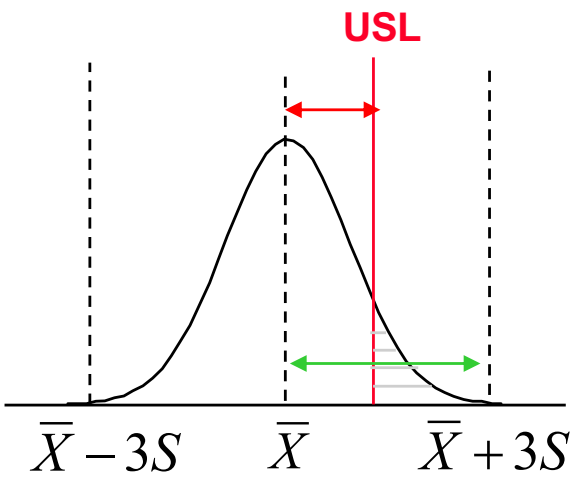
- Estimated out of spec proportion

  - Adjust a Normal distribution to the data
  - Calculate the probability to observe data out of the specification limits.

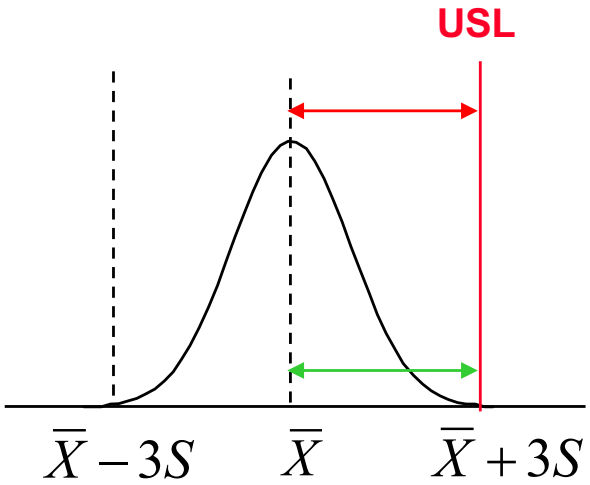


Cpu and Cpl indices for one specification limit

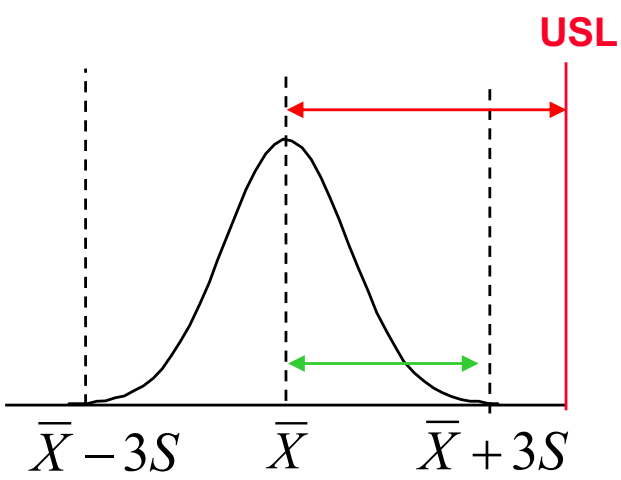
When there is only one upper specification limit : $Cpu = \dfrac{USL - \bar{X}}{3S}$



Cpu < 1



Cpu = 1



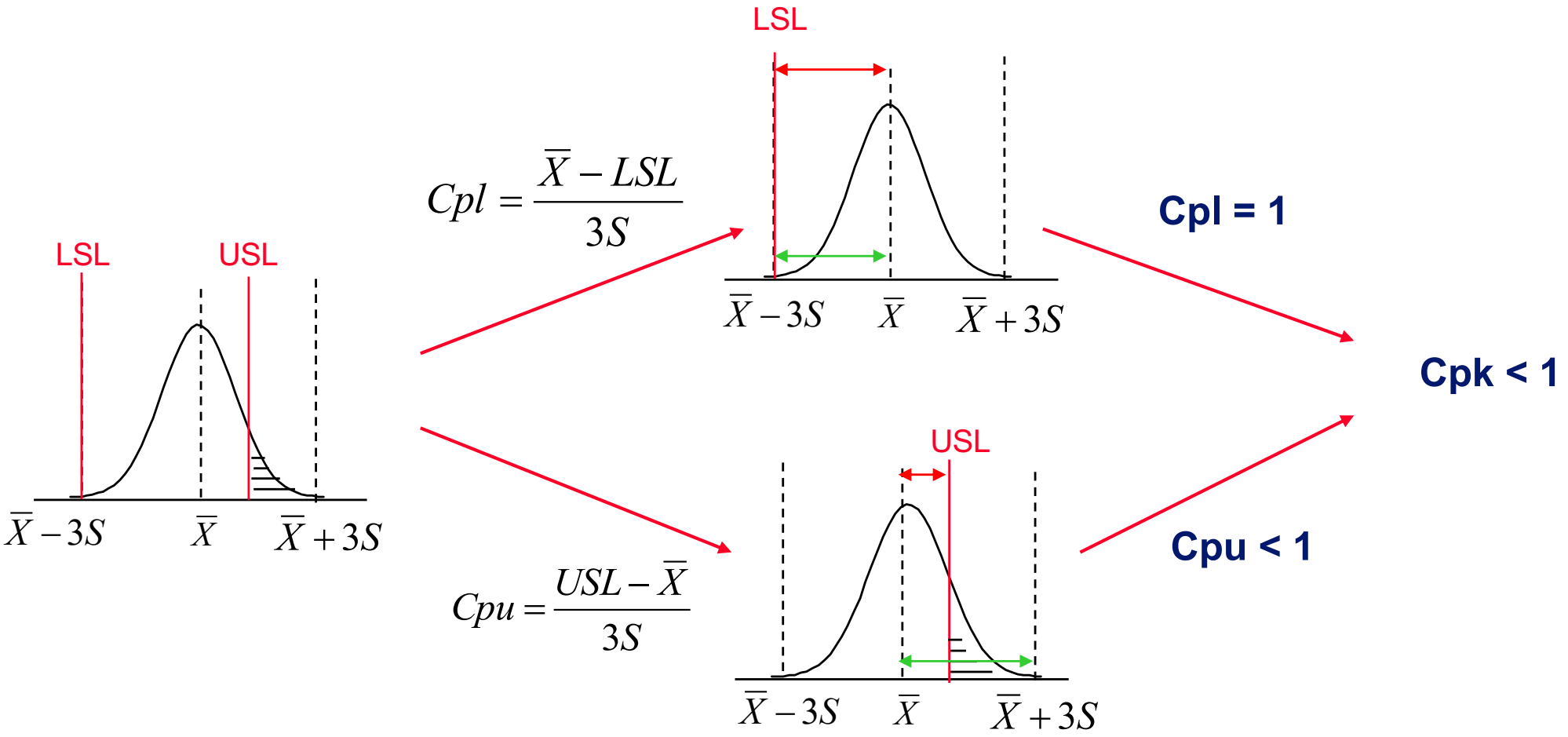
Cpu > 1

When there is only one lower specification limit : $Cpl = \dfrac{\bar{X} - LSL}{3S}$

Cpk index, a combination of Cpl and Cpu

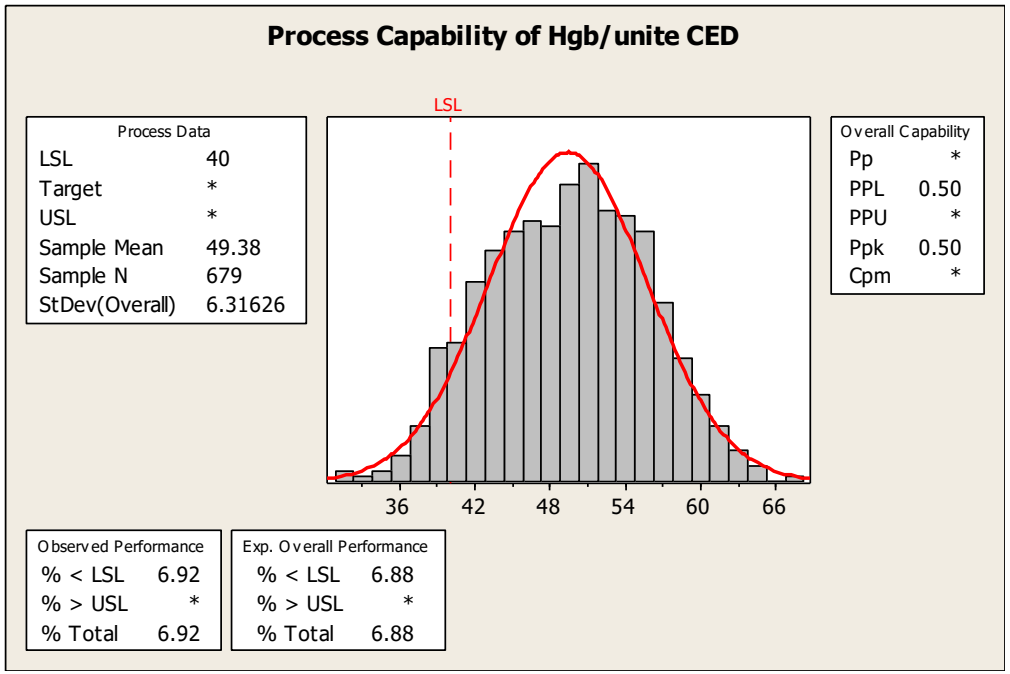
Cpk = min (Cpl, Cpu)

Good Cpk : Cpk > 1

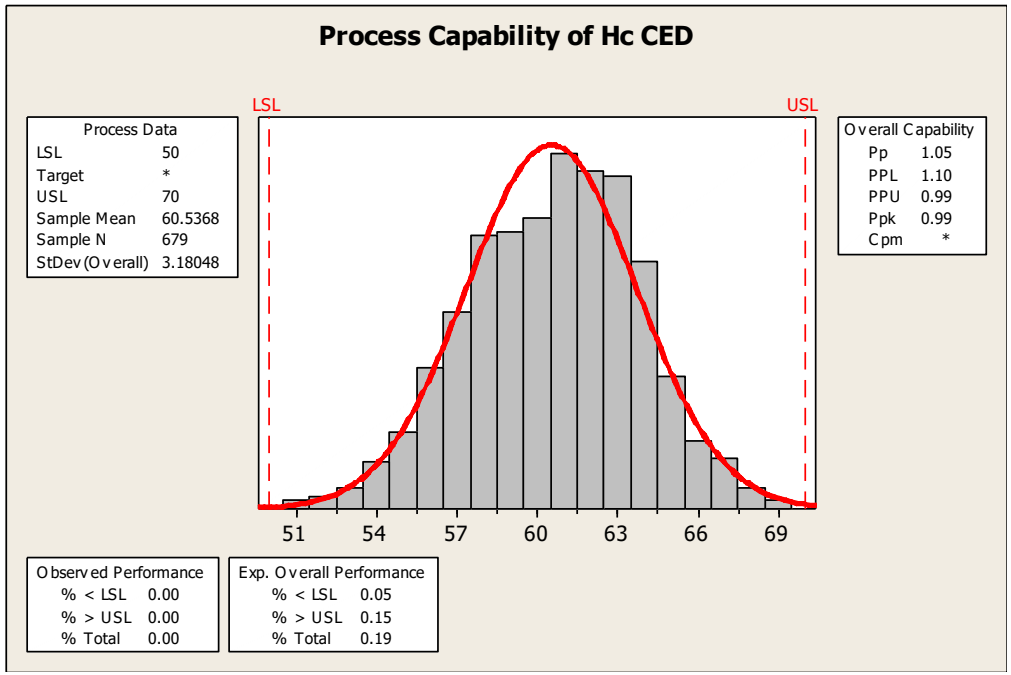


Capability analysis: examples

Hgb by CED Unit > 40

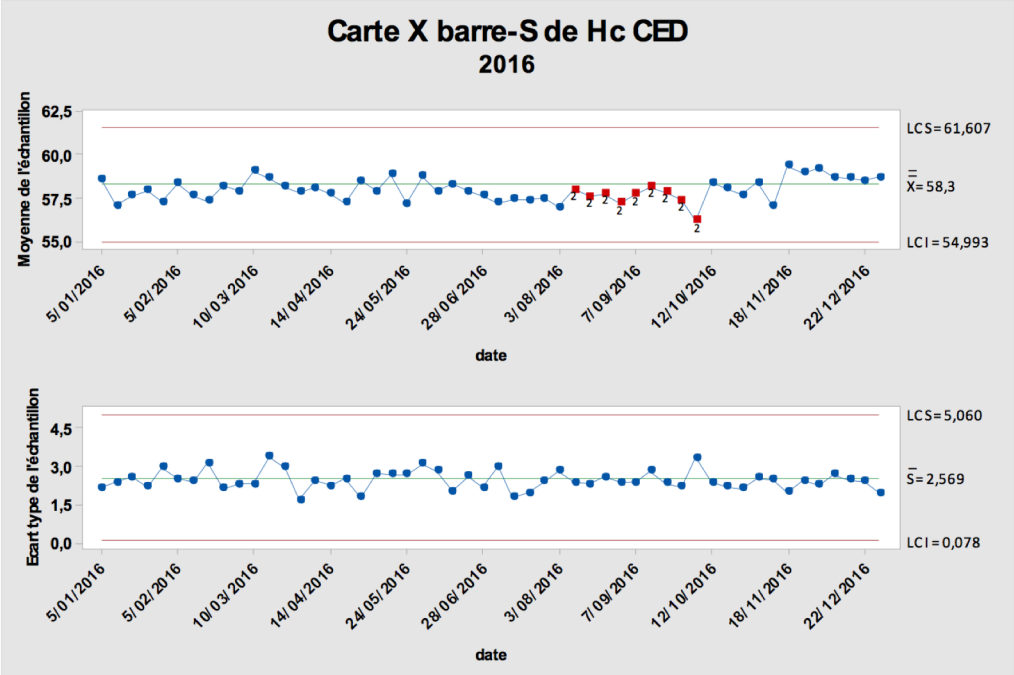


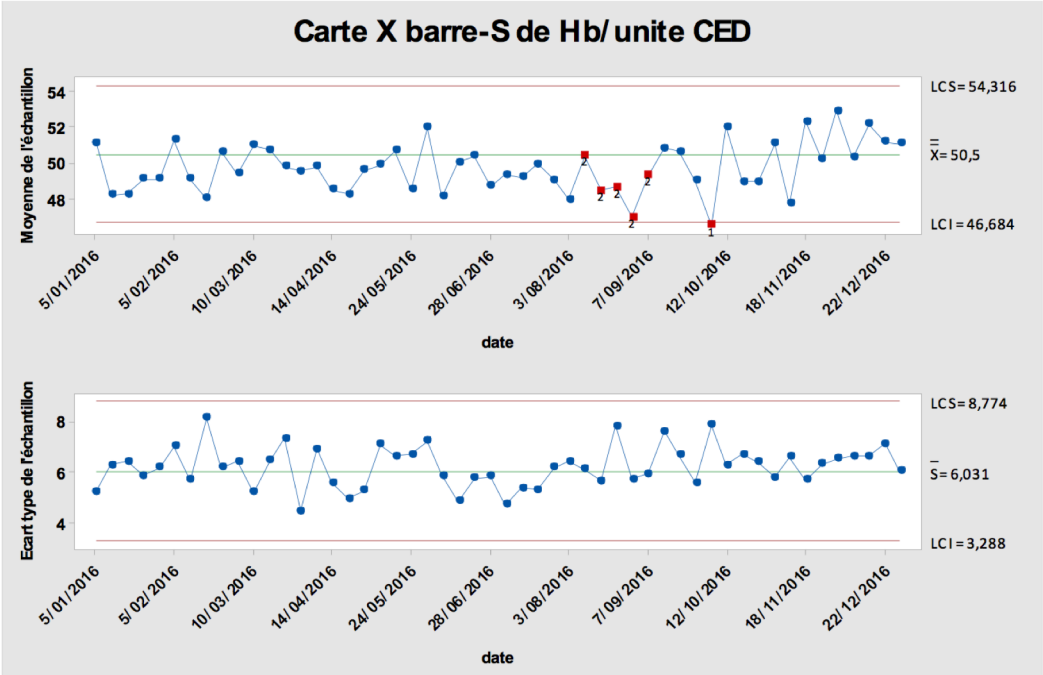
50 < Hc < 70



Quality control annual report at Belgian Red Cross

A monthly and annual report is prepared for each important variable including Cpk and %Out of spec measures.





Quarter	1st	2d	3rd	4th
Number	299	288	303	290
Mean	58,0	58,0	57,5	58,3
Standard-Deviation	2,6	2,5	2,4	2,5
LSL	50 < HC < 70	50 < HC < 70	50 < HC < 70	50 < HC < 70
Cpk (IC)	1,01 (0,92-1,10)	1,08 (0,98-1,17)	1,04 (0,95-1,13)	1,08 (0,99-1,18)
% performance obs	0,00	0,00	0,33	0,34
% performance exp	0,12	0,06	0,09	0,06

Quarter	1st	2d	3rd	4th
Number	299	288	303	290
Mean	49,7	49,6	49,2	50,4
Standard-Deviation	6,3	6,0	6,1	6,6
LSL	Hg > 40	Hg > 40	Hg > 40	Hg > 40
Cpk (IC)	0,51 (LI 0,46)	0,53 (LI 0,48)	0,51 (LI 0,46)	0,52 (LI 0,47)
% performance obs	5,35	4,51	6,93	5,86
% performance exp	6,33	5,48	6,48	5,84

Acceptance sampling to verify the conformity of a lot of incoming material or of the production with respect to the specification

Capability indices → Characterization

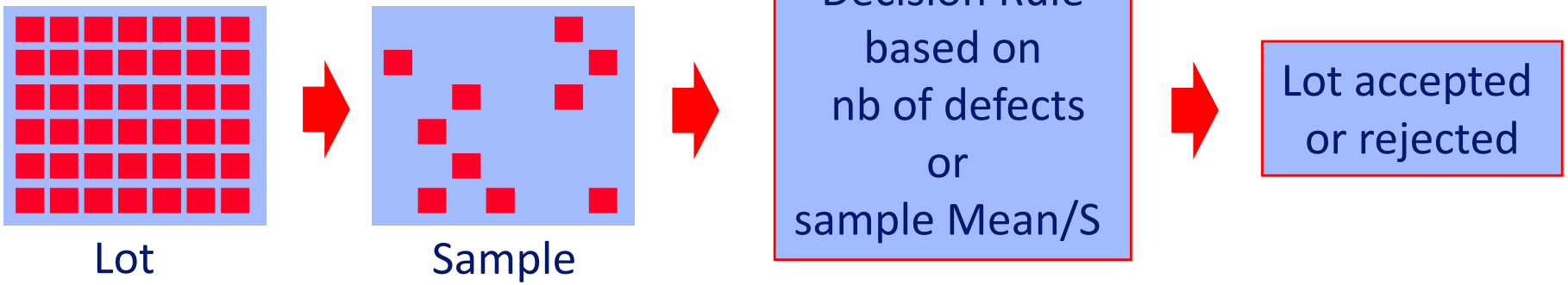
Acceptance Sampling → Decision

Objective of acceptance sampling

Goal of Acceptance sampling

« Verify that the supplier delivers lots of materials at a quality equal or superior to a level of quality (AQL) decided between the client and supplier (or imposed by the legislator) »

Principle



Applications

- Incoming material used in blood donation and transformation: e.g. lots blood bags, laboratories reagent kits,…
- Lots of blood products delivered to hospitals. E.g. one lot = one day of production of RBC or of PC, etc. …

Type of acceptance sampling

By attribute (e.g. visual check) or variable (a measure is done on each sampled unit)

Acceptance sampling international standards

- Acceptance lot-by-lot sampling methodologies are described very clearly in international ISO standardization texts in order to avoid any ambiguity in the applied procedures.

- Two standards are provided :
  - ISO 2859 for acceptance sampling based on an inspection by attribute data
  - ISO 3951 for acceptance sampling based on an inspection by variable


NORME INTERNATIONALE

ISO 2859-1

Règles d'échantillonnage pour les contrôles par attributs —


norme belge enregistrée

NBN - ISO 3951

2e éd., juillet 1993

Indice de classement : X 03

Règles et tables d'échantillonnage pour les contrôles par mesures des pourcentages de non conformes

Sampling procedures and charts for inspection by variables for percent nonconforming

- They provide different sampling schemes : simple, double, sequential

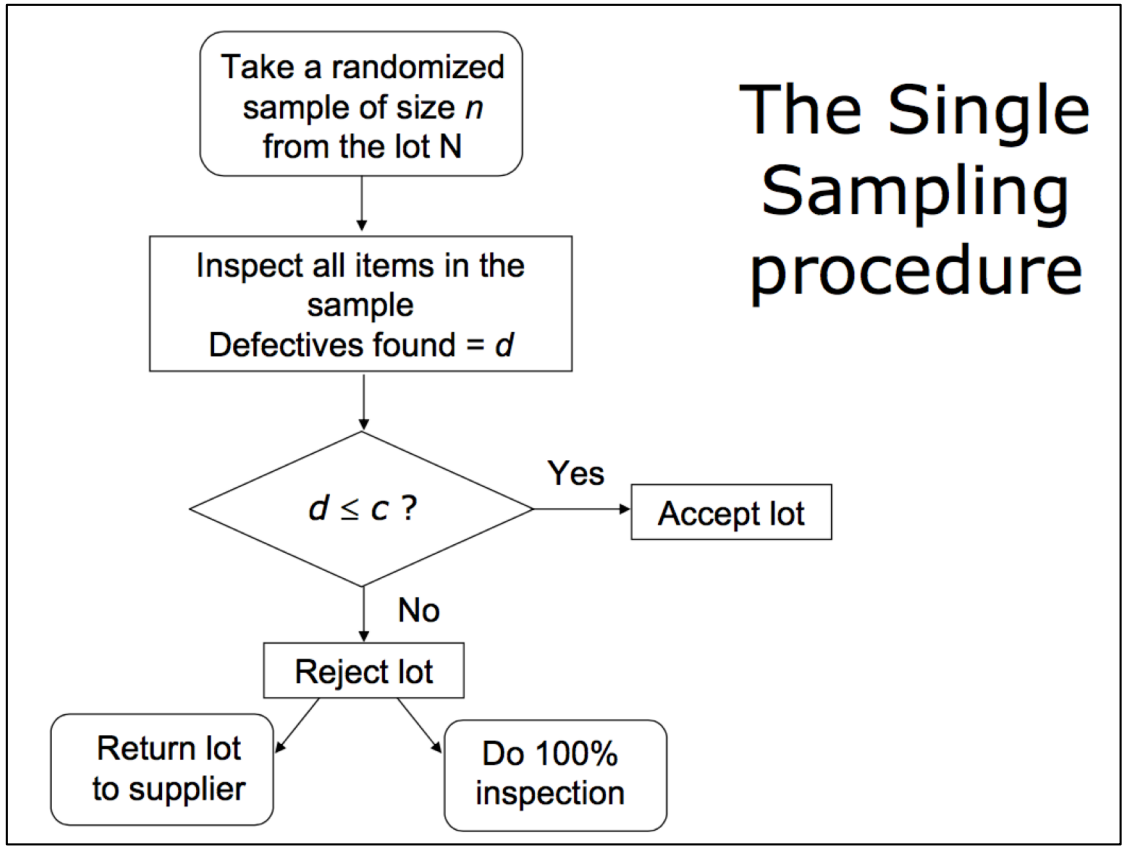
Parameters of a sampling plan for attributes

Input parameters

N : Size of the lot
AQL : Acceptable quality level
(% defects accepted)
Chosen level of inspection
Level 1 / 2 / 3 / S3 / S4
Normal/Reduced/reinforced

Sampling plan parameters

n : sample size
c : maximum number of defectives accepted



n and c computation based on client and supplier risks

Client and supplier objectives

- The client doesn't want to accept a lot with a proportion of defect p > AQL
- The supplier doesn't want to have one lot rejected when it is « good » : p < AQL

Computation of n and c

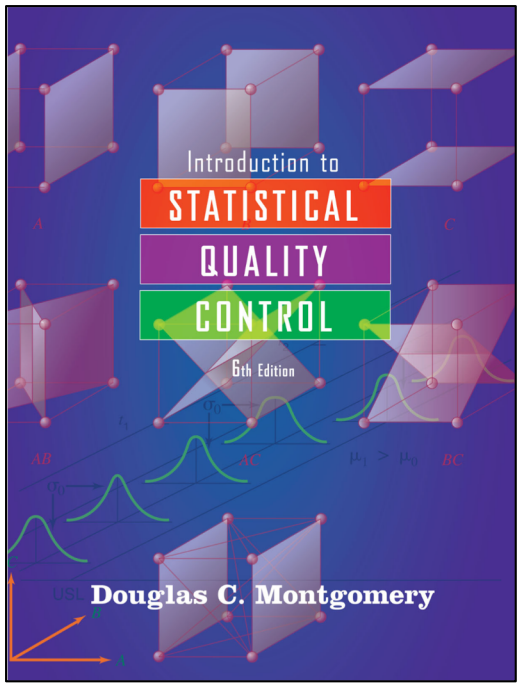
n and c are calculated in order to minimize (or at least control) the supplier and client risks to take a wrong decision.

		Lot	
		Good lot : $p \leq AQL$	Bad lot : p >AQL
Sample	$d \leq c$: Acceptation	Good decision	Client Risk
	d > c : Rejection	Supplier Risk	Good decision

Three questions: three classes of statistical quality control tools

Stability of the process over time	Control charts	X, Xbar-R, EWMA, p and Scan charts
Comparison of the production to the specifications	Capability analysis	% Non conform, Cpu, Cpl, Cpk
Conformity of a lot of material to the specifications	Acceptance sampling	Iso norms 2851 and 3951

References



Transfusion Medicine, 2009, **19**, 329–339 doi: 10.1111/j.1365-3148.2009.00942.x

ORIGINAL ARTICLE

Practical guidelines for applying statistical process control to blood component production

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An evaluation of statistical process control techniques applied to blood component quality monitoring with particular reference to CUSUM

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Thank you for your attention !
Do you have any questions ?