Utilization of Statistical Methods For Production Monitoring

Technical Report No.59

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1.0 Introduction 简介

As manufacturers seek to improve the quality of their goods， statistical methods have been rediscovered as vital tools for successful development and manufacturing. Industries like automotive， electronics， and consumer products grow and change partly as a result of adopting statistical methods.
随着生产商期望提高产品质量，统计方法逐渐成为开发和生产成功的重要工具。汽车、电子、消费品行业也部分因为采用统计方法发展和改变。

The pharmaceutical and biopharmaceutical industry increasingly recognizes the importance of statistical methods to consistently create products that conform to predetermined quality characteristics. Statistical methods provide objective evidence in meeting this goal and are fundamental for understanding the process，which enables further improvement and development.
制药和生物制药工业越来越认识到统计方法的重要性，以持续生产符合预定质量标准的产品。统计方法为符合这一目的提供了客观证据，也是理解工艺的基础，使持续改进和开发成为可能。

Industry and regulatory bodies are working together to provide guidance and frameworks on the use of statistical methods. The International Conference on Harmonization， International Standards Organization and European Union have provided guidance on the use of statistical methods.
工业和监管部门正在一起努力建立统计方法使用指南和框架。ICH、ISO、EU 已经有了统计方法的指南。

In light of the increased focus on this topic， this PDA Task Force recognized the need to provide guidance to help companies identify and use statistical methods. The primary objective of this Task Force was to convey the appropriate use of statistical methods at a level most can understand.
鉴于人们对这一主题越来越重视，PDA 工作组认识到应该建立指南帮助公司识别和使用统计方法。该工作组的基本目的是让大多数人能够适当应用统计方法。

1.1 Purpose and Scope 目的和范围

The purpose of this document is to present relevant and easy-to-use statistical process control (SPC) methods that are applicable to the pharmaceutical/biopharmaceutical industry. Advanced statistical methods， such as multivariate models and Design of Experiment (DoE) will not be considered. An overview of acceptance sampling is also included in Section 4.0.
本文件是为了提供的相关、易用的统计过程控制方法，以应用于制药/生物制药工业。 高级统计方法，如多变量模型和试验设计（DoE）不包含在内。4.0 节对接收取样进行了概述。

1.2 Implementation to Support Decision Making 利用统计方法为决策提供支持

Statistical methods are intended to improve the quality of decision-making. They are simply a means to a result. If the manufacturer does not first understand why it is utilizing a statistical method， problems such as failing to detect important signals or over-detecting unimportant normal variation can occur. Caution should be exercised to first establish the question to be answered and then statistical method to aid in answering the question.
统计方法可用于提高决策质量。它们只是达到结果的一种手段。如果生产商没有理解为何采用统计

方法，就可能出现无法检测重要信号或过度放大微小、正常的变动。应注意首先确定需要回答的问题，再采用统计方法帮助回答问题。

The statistical methods may be used in an ongoing program to analyze collected data. Timely evaluation of data allows the prompt detection of undesired process variation， which facilitates process understanding and may support responses to control variability.
统计方法也可用于一个持续计划中对收集的数据进行分析。及时进行数据分析能够迅速发现非预期的工艺变动，增加对工艺的理解，并及时采取措施对变动进行控制。

To best aid the end-user， each statistical method is described in the following format:
为了更好地帮助用户，每一统计方法按以下形式论述

- Description 描述
- Pros and Cons 优缺点
- Typical Applications 典型应用
- Technical Details and Examples (see appendices)技术细节和举例（见附件）

The guidance contained in this document is not intended to establish mandatory standards for using statistical methods across a product's lifecycle.
本指南不用于建立产品生命周期内统计方法应用的强制标准。

2.0 Glossary of Terms 术语表

Some of the key concepts are illustrated below; additional explanation will be in subsequent sections
以下介绍了部分主要概念，进一步解释见后续章节。

Limits 限度

There are different types of limits to be considered. Some are binding (specification limits); others are for orientation (process control limits).
有不同类型的限度，有的具有约束力（质量标准）；其他的用于指导目的（过程控制限度）。

Specification limits 质量标准

Specification limits are set by the manufacturer based on therapeutic product and regulatory requirements. ICH Q6A defines specification as: A list of tests， references to analytical procedures， and appropriate acceptance criteria which are numerical limits， ranges， or other criteria for the tests described. 1t establishes the set of criteria to which a drug substance or drug product should conform to be considered acceptable for its intended use. “Conformance to specifications” means that the drug substance and / or drug product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities. (1，2).
质量标准由生产商基于药品和监管部门要求制订。ICHQ6A 将质量标准定义为：一个测试清单，参考对应的分析步骤，以及以数值、范围或其他测试标准表示的适当的可接受标准。它建立了一系列标准，为了符合预定用途药物必须符合这些标准。符合标准意味着药物按照所批准的分析步骤检测时，可以符合可接受标准的要求。质量标准是生产商提出，证明其合理性，并得到监管部门批准的关键质量要求(1，2)。

Specification limits 质量标准:

- Denote the boundary between acceptable and unacceptable， the quality threshold.
  指示合格和不合格界限，质量阈值
- Describe what the process must achieve. When specifications are exceeded, there is a loss of value, time or cost.
  描述了工艺必须达到的要求，当超出限度要求时，就会有价值、时间的损失或成本的增加。
- Should be driven by therapeutic effect and toxicological impacts as relevant to the patient. Specifications control risk to the patient
  应根据治疗效果和毒理作用制订。质量标准应能控制对患者造成的风险。

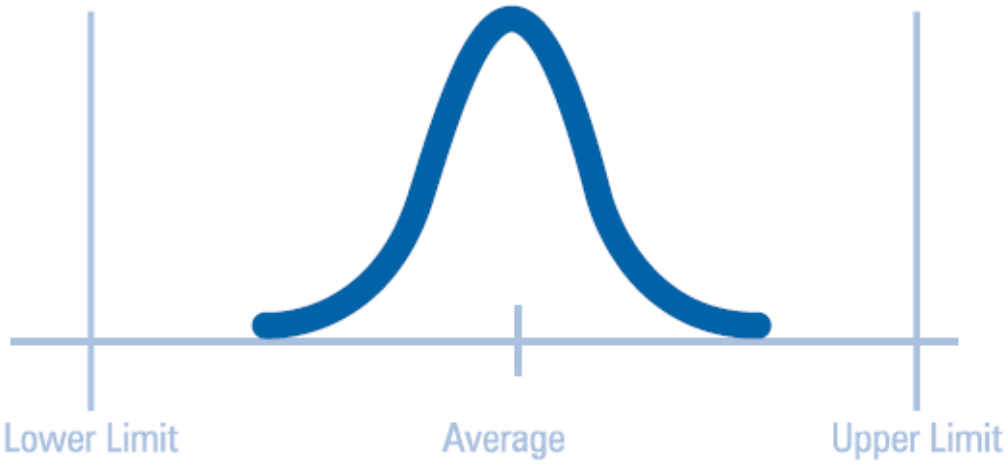
Process Capability 过程能力

Process capability descries how the process performs in relation to the specifications.
过程能力描述了过程如何符合质量标准相关要求

High Capability Processes 高过程能力

High capability processes have low inherent variation relative to the specification or goal. When a number of results are plotted on a histogram， it is unlikely that there will be many result occurrences near the specification limits.
高能力过程与质量标准有关的固有变动较小。当采用一定数量结果作直方图时，不会有许多结果出现在限度附近。

Figure 2.0-1 Example of a High Capability (Low Variability) Process Capability Histogram
高能力（低变动）过程能力图

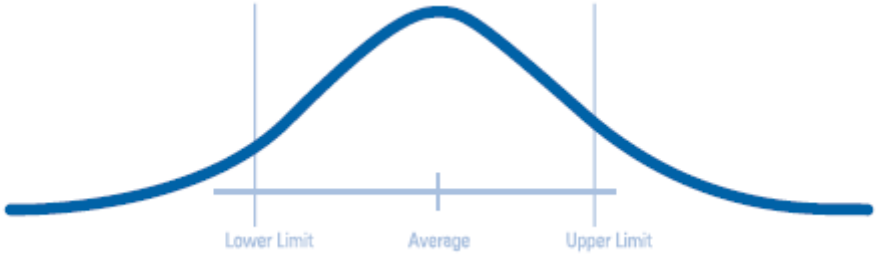


Process Capability (cont.) 过程能力（续）

Low Capability Processes 低能力过程

Low capability processes have greater inherent variation relative to the specification or goal. When a number of results are plotted on a histogram， it is likely that results will occasionally occur beyond the specification limits.
低能力过程与质量标准相关内在变动较大。当用一系列结果作直方图时，结果有可能超出限度范围。

Figure 2.0-2 Example of a Low Capability (High Variability) Process Capability Histogram
低能力（高变动）过程能力图



Statistical Process Control Limits 统计过程控制限度

Statistical process control limits are statistically derived measures that are used to define the typical operating range for the process. Process control is the focus of this document. Unlike specification

boundaries which are related to product impact， control limits are boundaries that annunciate when process performance may have shifted.
统计过程控制限度是用于确定常规工艺操作范围的统计措施。过程控制是本指南的重点。质量标准限度与产品功能有关，而控制限度能提示工艺性能的漂移。

Process control limits 过程控制限度:

- Denote the boundary between typical and unusual operational performance ranges for the process.
  指示典型工艺操作范围与异常工艺操作范围的界限

- Are calculated from prior performance data and used to detect when a process is unstable or "out of statistical control".
  通过历史操作数据计算而得，用于监测工艺是否不稳定，或超出统计控制范围

The prompt recognition of deviations from typical performance enables review. The review can lead to an understanding of how a process may be improved. It is essential to understand that process control boundaries only relate to the ability to discern numerical differences. They are not equivalent to specification limits that describe the conformance / non-conformance boundaries. Statistical significance is also not the same as practical significance, which is a difference that has a meaningful impact on the process. Depending on the circumstances of the process, when there are sufficient samples present, it is possible to detect statistical differences that have no practical importance. It is also possible in processes with tight specification limits and noisy measurement systems for it to be challenging to detect important performance changes. The users of process control tools must apply their understanding of the process when evaluating the relevance of process control detections.
迅速发现偏离典型操作范围有助于及时进行回顾。回顾能够加深对工艺的理解，并改进工艺。关键要理解过程控制界限仅与区分数值差异的能力有关，而质量标准则不同，质量标准规定了符合/不符合界限。统计学意义与实际意义也不同，这种不同将对工艺造成影响。根据工艺条件不同，当有足够样品时，也可能检测到一些无关紧要的统计学差异。严格质量标准限度和噪声测量系统也可能检测出重大工艺性能变化。使用过程控制工具时，应根据对工艺理解，进行过程控制结果的相关性评估。

Statistical Process Control Limits (cont.) 统计过程控制限度（续）

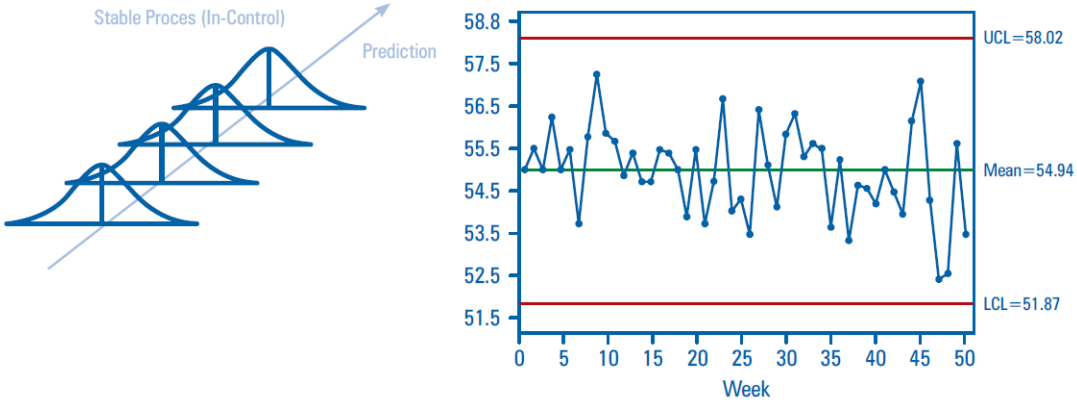
Stable Process (Statistically In Control) 稳定工艺（统计学意义上受控）

Stable Process (statistically in control) is a process that is consistent and predictable. It does not exhibit special (or assignable) cause variation as identified through the use of statistical techniques. The variation present is due to only common cause variation
稳定工艺（统计学意义上受控）是指稳定一致且可预测的工艺。它不会发生特殊（或可指明）原因的变动，这些变动可通过统计技术的应用而发现。现有的变动仅由于正常原因变动构成。

Figure 2.0-3 below shows a stable process (statistically in control). The distribution of the process is consistent over time (as shown on the left). Each successive outcome is random， but aligns with the expectation for the process.

下图 2.0-3 显示了一个稳定工艺（统计学意义上受控）。在整个时间范围内结果分布是一致的（如左图所示）。每一个连续结果是随机的，但都与对工艺的预期保持一致。

Figure 2.0-3 Examples of a Stable Process (Statistically In Control) 稳定工艺（统计学意义上受控）

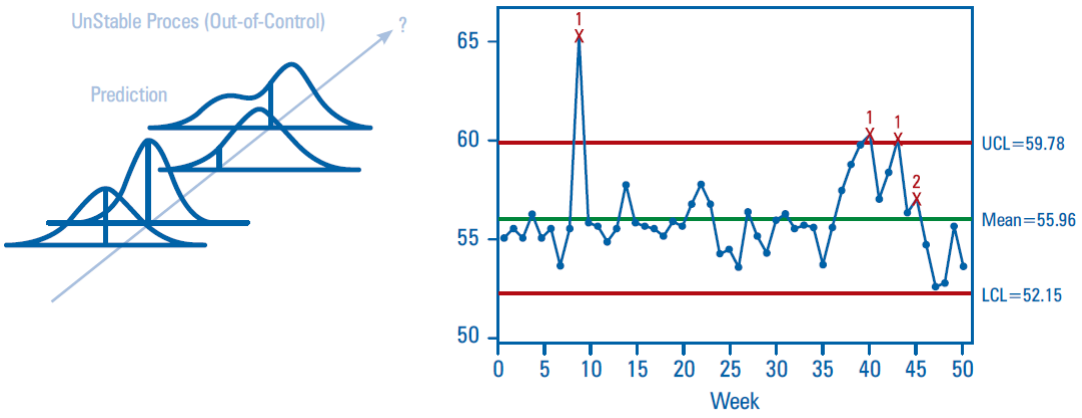


Unstable Process (Statistically Out of Control) 不稳定工艺（统计意义上不受控）

Unstable process (statistically out of control) is a process that is not consistent or predictable. It exhibits special cause variation as identified through the use of statistical techniques. This is also sometimes called "Out of Trend"， where the current performance is detected to be not part of the prior (level，uniform) trend. Figure 2.0-4 below illustrates an unstable process. The distribution of the process is not consistent over time (as shown on the left). Each successive outcome is random， but does not align with the expectation for the process.

不稳定工艺（统计意义上不受控）是一种一致或无法预计的工艺。通过应用统计技术，可以发现特殊原因变动。有时也称作“趋势异常”，这时可发现现有结果与以前趋势（水平的，均一的）不一致。下图 2.0-4 显示的是一个不稳定工艺。在整个时间范围内结果分布不一致（如左图所示）。每一连续结果都是随机的，但与工艺期望值不一致。

Figure 2.0-4 Examples of an Unstable Process (Statistically Out Of Control) 不稳定工艺（统计意义上不受控）



Statistical Process Control Limits (cont.) 统计过程控制限度（续）

Warning or Alert Limits 警戒限

These types of limits are determined and used typically during development， environmental or manufacturing process monitoring for the purpose of detecting trends or to get a better understanding of the manufacturing process and its consistency. These limits are usually not intended to require a formal investigation， a report or an involvement of Quality Assurance in case of detection. In some instances (e.g.， microbiological monitoring) a Standard Operating Procedure (sop) can define follow-up steps that may include actions, such as increased frequency of testing or possibly proactively increased actions to mitigate risk of future impact.

这类限度一般在开发阶段、环境控制或生产工艺控制中制订并使用，以监测趋势或获得对生产工艺及其一致性的进一步理解。超出这些限度一般不需要进行正式的调查，报告或 QA 的参与。某些情况下（例如，微生物监控），可在一个标准操作程序确定后续措施，包括采取的行动，如增加测试频次或主动降低风险措施

Variability 变动

Variability is categorized here by two types; i.e.， common cause and special cause. It is important to recognize the distinctions when understanding a process and taking the appropriate action to improve the process.

变动分为两类：即普通原因和特殊原因。加强对工艺的理解，并采取措施改进工艺时，重要一点是能够区分这两类变动。

Common Cause Variability 普通原因变动

Common cause variation is the result of the combination of all of the typical variability in the materials，process and measurement system. These many small components of variation are expected to be present in the manufacturing process.

普通原因变动是物料、工艺、测量系统所有典型变动共同作用的结果。在生产工艺中可以预期这些微小变动。

Special Cause Variability 特殊原因变动

Special cause variation is a change caused by special circumstances not expected from the process. These occurrences are not predictable， and may come and go sporadically. Special cause events are detectable when compared to statistical control limit techniques， hence the term used to denote this condition is described as "out of statistical control" (limits). The prompt detection of special causes allows the proper investigation and evaluation of impact to subsequent production or downstream processes.

特殊原因变动是正常生产过程不会发生的特殊情况导致的变更。这些事件是无法预期的，只是偶然发生。与统计控制限度比较，就可发现特殊原因事件，因此这种情况被称为“统计控制超标。迅速发现特殊事件后，可及时进行适当调查，评估对后续生产或下游工艺的影响。

Trends 趋势

Trends are changes in the average or variability of the result. An analysis of data often exhibits an ongoing upward or downward pattern that is not due to random noise. Analyzing trends is useful in

detecting patterns that could lead to future quality problems， and in anticipating upcoming performance. Statistical process performance monitoring tools as defined in this document can be used to detect trends using objective numeric tools.
趋势是结果平均值或变动的一种改变。数据分析通常呈现为持续向上或向下的图形，这并不是由于随机噪声导致的。对趋势进行分析有助于发现可能导致后续质量问题，估计后来的工艺性能。利用客观数据，本文中的统计过程控制工具可用来发现工艺趋势。

In the interpretation of GMP requirements， regulatory authorities increasingly request an assessment of trends in inspections. The prompt detection and evaluation of trends (3) supports the implementation of corrective and preventive actions (CAPA) as suggested by ICH QI0 (4). There is always an uncertainty if a trend is relevant to product quality. When establishing monitoring practices， the potential impact of process shifts should be considered when balancing risks of failure to detect potential hazards versus the risk of annunciating unimportant changes. "The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk" described as the second principle of ICH Q9 (5).
根据 GMP 要求，监管部门在检查中逐渐要求对趋势进行评估。迅速发现趋势（3）并进行评估，为 ICH Q10（4）中建议的纠正预防措施的实施提供支持。如果一个趋势与产品质量有关，总会存在不确定度。当建立监控程序时，应考虑工艺漂移的潜在影响，平衡未能监测潜在危害的风险与发现微小变动的风险。如 ICH Q9（5）第二条原则所述，“质量风险管理过程努力的程度、形式和形成的文件应与风险的级别相适应。

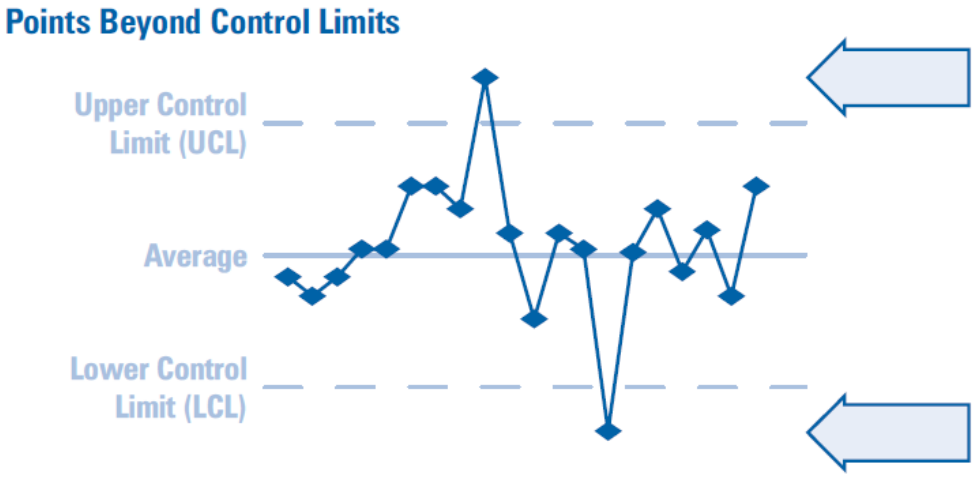
Some examples of trends are shownI in Figures 2.0-5 and 2.0-6.
图 2.0-5 和 2.0-6 为部分趋势示例

Points beyond control limits (not “specification limits”) which are isolated high or low points.
超出控制限（不是质量标准限度）的高值或低值。

Variability: Trends (cont.) 变动：趋势（续）

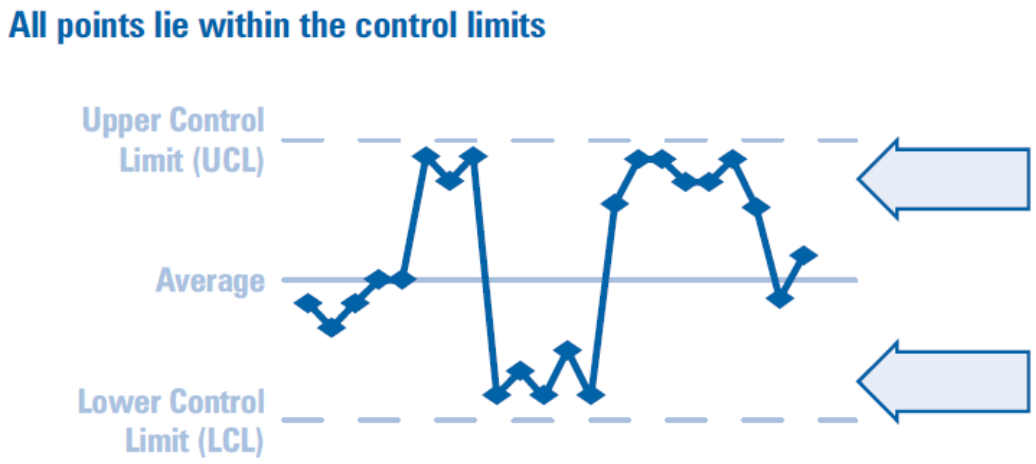
Figure 2.0-5 Examples of Trends (Points Beyond Control Limits) 趋势示例（超过控制限的点）

Points Beyond Control Limits 超过控制限的点



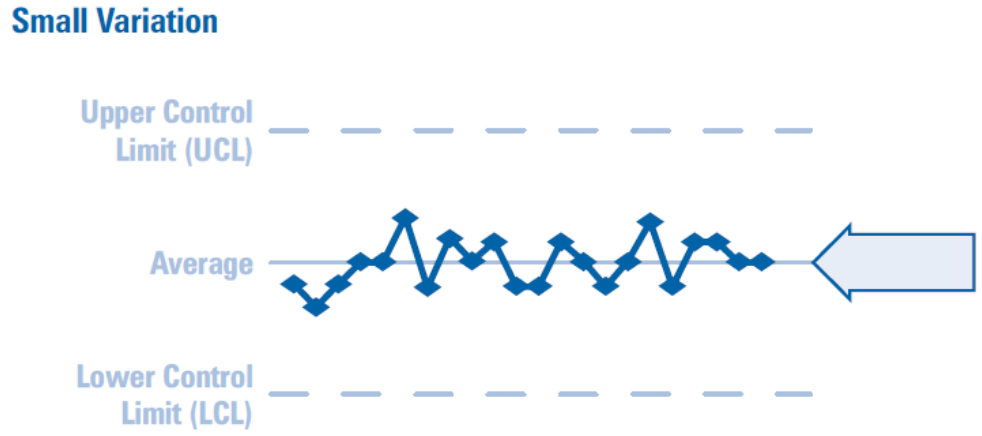
If all points lie within the control limits， there are still features that may be of process interest. Erratic ups and downs in groups of points with sparse values in middle.
如果所有点都处在控制限内，仍有部分特性与工艺相关。如一组数据中有些忽上忽下，而中间水平数据很少。

Figure 2.0-6 Examples of Trends (Points within the control limits) 趋势示例（所有点处在控制限内）
All points lie within the control limits 所有点处在控制限内



Variation small compared to control limits - where almost all of the points are within ne-third (of the distance between the control limits) of the centerline.
与控制限比较变动很小-几乎所有点在中线 1/3（控制限之间的距离）以内

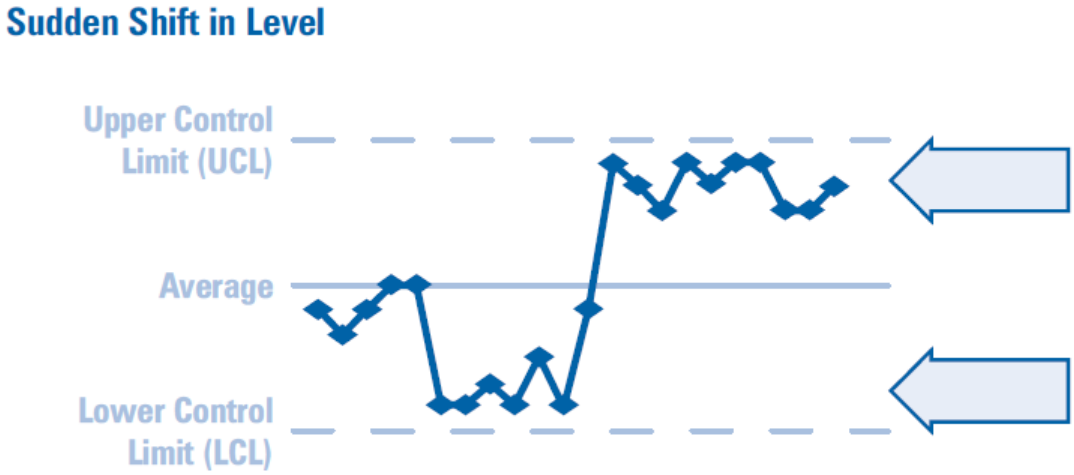
Small Variation 较小的变动



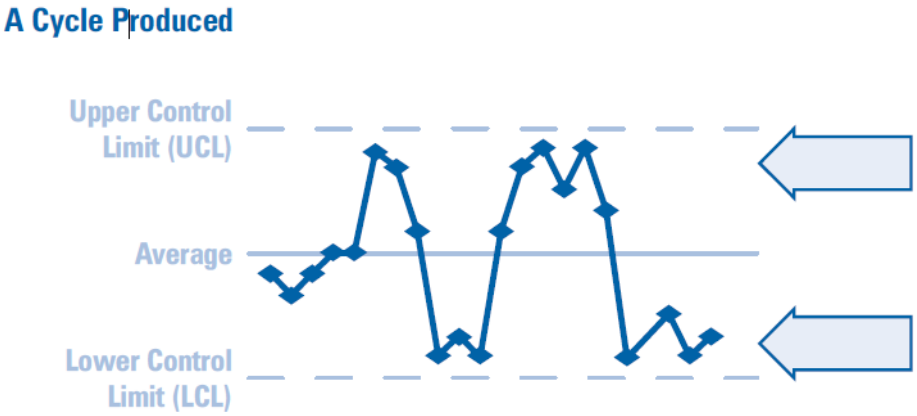
Variability: Trends (cont.) 变动：趋势（续）

Sudden shift in level where the points seem to move to a new average over a short period of time.
在较短时间内，数据平均水平突然出现变化。

Sudden Shift in Level 平均水平的突然变化



A **cycle** produces a pattern of up and down points， as though the values of the points were time dependent.
一个周期内数据点有上有下，似乎数值与时间有关。



There are several systems of "rules"， such as in the examples listed above， that can be applied to detect non-random conditions. These may present opportunities to increase process understanding by allowing appropriate reaction. Two of the more common sets include the Western Electric rules， and the Nelson Rules. For every additional criteria applied to the evaluation of data， there will be more “false positive” detections. It is, therefore, appropriate to evaluate the potential benefit, and apply only the rules that are relevant for that process situation. The use of rules helps ensure a consistent threshold of detection， and can be a useful mechanism to annunciate potential events for review. These rules are typically evaluated as each new data point is added; they typically reference regions which are defined as standard deviations around the process mean.
有几个“规则“系统，如上述示例，可用于检测非随机情况。通过采取适当措施，为增进工艺理解提供了机会。两个最常用的工具包括西部电气规则和纳尔逊规则。对于其他数据评估标准，可能出现更多”假阳性“结果。因此，应对工具的优点进行评估，选择适用相应工艺的规则。规则的使用

有助于建立一致的检测阈值，发现潜在事件并进行评估。每增加一个数据点，都应重新进行评估，它们通常引用区间的概念，区间指过程平均值两边标准偏差的范围。

3.0 Statistical Process Control Tools 统计学过程控制工具

The following sections introduce some of the more common statistical methods for monitoring manufacturing processes. Most of these methods involve plotting the process data or a statistic calculated from those data on a chart. The vertical axis of the chart represents the dependent range of values in the process data or the statistic calculated from the process data. For many of these tools, the horizontal axis represents the independent timing of the data being plotted. It is important to arrange and then plot the data in "time-order," as close as possible to the date and time the data were actually generated. Control charts are often plotted by date manufactured to better illustrate potential patterns in production, review by date tested may be appropriate for monitoring measurement systems. Since the primary purpose of process monitoring is to ensure that the process remains in a state of statistical control, most of the methods include the addition of limits or numeric boundaries that provide one way of assessing control. All of the charts can be examined for data patterns which may indicate when a process is not in a state of statistical control. There are several statistical software packages that create the charts described, and even when these are used, an understanding of the underlying principles will aid in the appropriate selection and application of statistical tools (see **Table 3.0-1**). For each method, typical applications, technical details and the pros/cons are presented (see **Table 3.0-2**).
以下几个章节介绍了几种监控生产过程比较常用的统计学方法。其中绝大多数是采用将原始数据或原始数据的处理结果来画图的方式进行。纵坐标为原始数据或其统计处理结果相关范围的值。横坐标一般为采集这些数据的时间。按时间顺序作图非常重要，尽量做到实时作图。控制图经常在生产当天结束完成，以更好说明潜在的生产模式，对于监控测量系统，检验结束当天进行回顾比较合适。由于过程监控的主要目的是确保生产工艺维持在统计学受控状态，绝大多数方法包括增加限度或数字边界以提供评估控制的方式。所有的控制图可用于检查数据模式，这些数据模式可能显示一个工艺已经不在统计学控制状态。有好几种统计学软件包用于创建所说的控制图，而且即便是使用了这些软件，理解内在的规则对选择和应用这些统计学工具也是有帮助的。（见表格 3.0-1）。对于每种方法，本技术报告提供了典型应用、技术细节以及有利及不利的方面（见表 3.0-2）。

3.0.1 Prerequisites for Data Analysis 数据分析前提

Any meaningful statistical evaluation has several prerequisites:
任何有意义的统计学分析都有以下几个前提：

- The data integrity is assured and the measurement system is acceptable. The analytical method creating the results assures a valuable set of data (e.g., accuracy, precision, repeatability, specificity, detection limit, and quantitation limit are understood and maintained).
  数据完整性有保证，检测方法可靠。分析方法获得的结果确保是一组有价值的数据（例如：分析方法有充分的准确性、精密度、重复性、专属性、检测限以及定量限）。

- The attributes where statistics should be applied are meaningful for the expected information. The data describe critical process parameters (CPP) or critical quality attributes (CQA) (see also ICH Q8/Q11 and Q10) *(4,6,7)*.
  需要使用统计学分析的指标对于期望获得的信息是有意义的。这些数据描述关键工艺参数（CPP）或关键质量属性（CQA）（见 ICH Q8/Q11）（4、6、7）。
- The level of effort, formality and documentation in the use of statistical tools should be commensurate with the level of risk (based on ICH Q9) (S).

应用统计学的投入程度、正式程度、以及记录应与风险级别相称（ICH Q9）（5）。

- Results should maintain the order of production, so that trends which evolve over time are apparent.
  结果应按照生产先后顺序排列，这样随时间的趋势才会明显。

- The means by which a sample is taken and measured are defined so that the sample accurately highlights important features of the process. The design of the sampling approach should ensure that relevant sources of variability can be detected. If there are potentially important differences between multiple samples, consider strategies for grouping. This is described as the "rational subgroup." To effectively select groups, one must also have reasonable knowledge of the process and an understanding of the sources of variability. The selection of a rational subgroup will maximize the chance of detecting differences between groups and minimize the differences within a group.
  取样方式及检测方法应详细定义，这样样品才能准确显现工艺的重要特性。取样方式的设计应能体现出样品来源不同。如果多样品之间有潜在的重要差异，则应考虑将样品分组。这被称为“合理分组”。为有效选择小组，人员必须对工艺有充分的理解，并且了解差异的来源。选择合理小组将增大检测出组与组之间差异及缩小检测出组内差异的机会。

Groupings may support comparisons such as:
分组可能支持如下比较：

- **Lot to Lot** — common in parenteral manufacturing where a 'hatch" may be a certain (homogeneous) volume of liquid progressing through manufacturing steps.
  批与批：对于注射剂，通常指的是一定体积的均质溶液通过一定工艺进行处理后成为一批。

- **Time to Time** — this compares processing at one time to another, possibly within a batch. This may be samples within a lot (e.g., verifying homogeneity of liquid filled vials during a fill) or across broader divisions (e.g., between manufacturing campaigns).
  时间与时间：指的是将一段时间的数据与另一段时间相比较，可能指的是批之内不同时间段。这可以是一批之内的数据（例如：确认灌装期间液体的均一性）或更宽一点范围（如：连续批生产之间）。

Comparisons could also evaluate variability by comparing measurements within a item, across items, between production lines, plants or products.
比较也可通过比较一个项目或多项目用于评估生产线、厂房或产品之间的差异。

Table 3.0.1-1 Suggestions and Proposals on When to Use Statistical Tools 何时使用统计工具的建议和意见

The chart uses the following notation: + + for "preferred tool"; + for "useful"; o for "could be used"; — for "not to recommended"; for " not useful"; () for "depending on the individual process".

These considerations do not create new requirements.

表格用下列符号：++表示“推荐的工具”；+表示“有用的”；O 表示“可用于”；-表示“不推荐”；——表示“没用的”；（）表示“视具体工艺情况”。这些考虑不创造新的需求：

Areas of potential implementation 潜在应用区域	Characteristics for statistical purposes 统计学目的特征	Run Charts 运行图	Data Distribution数据分布	Individual Control Charts 单个数据图	Moving Range Control Charts 移动范围控制图	Histogram 柱状图	Process Capability 工艺能力	EWMA*	CuSum Charts** 累积和图
Pharmaceutical process development 药品工艺开发	Few lots/batches under the same process conditions 相同工艺很少批次	+	+			−	−	−	−
PAT implementation PAT应用	Real time data 实时数据			+			++	+	+
During Commercial manufacturing 商业生产	Historic data available 可获得历史数据			++	++	++	++		++
Stability studies 稳定性研究	Few data over the years only 很多年只有很少数据						−−		−−
Process Validation 工艺验证	Large data pool from a few lots/batches only 从较少的批次中获得的大量数据		+			0	+		
Continuous process verification 持续工艺验证	Continuous big data pool 持续获得大量数据			++	(+)		(+)	+	++
In process control (IPC)过程控制	Back log analysis (1d) 累积分析（1天）			++	0	+			++
Yield Trends 收率趋势	Can be noisy, shifts in average are relevant to business 可以是噪音，商业相关的平均值变化			+				++	+
Microbiological testing 微生物测试	Time lag to any analysis (1 week); no NONNORMAL distribution in the material 对任何分析均有滞后性（1周）；在物料中不是非正态分布需要统计适合于非正态分布。非参数工具不在本文讨论范围。常规放行检验累	Requires statistics suited for non normal distributions. Non-parametric tools are outside scope of this document. 需要统计适合于非正态分布。非参数工具不在本文讨论范围。							
Conventional release testing 常规放行检验	Backlog analysis (1week) 累积分析（1周）			+			0		(+)
Real time release testing 实时放行检验	Backlog analysis (1week)				+		+		
Real time release testing	Lot of data in a short time 短时间大量数据								
Annual Product review 年度产品回顾	Historic evaluation 历史评价				++	++	++		−−

* Exponentially Weighted Moving Average (EWMA) 指数加权移动平均

** Cumulative Sum (Cu Sum)累积和

Table 3.0.1 - 2 Areas of Potential Implementation

潜在的应用领域

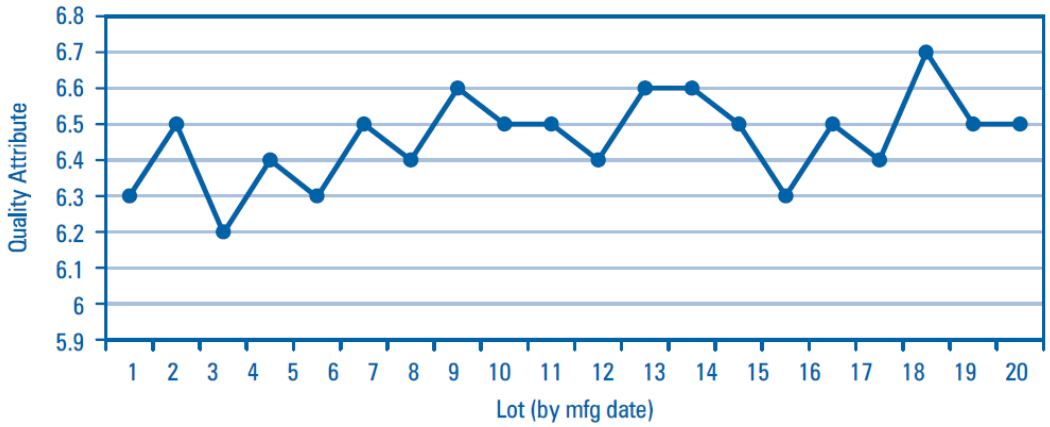
Statistical tool 统计工具	Strength 优势	Purpose 目的	Awareness of statistical challenges 对统计挑战的认识
Run Charts 运行图	Mapping of data 数据分布图	Look for evidence of patterns in process data 寻找工艺数据模型证据	Interpretation of trends 趋势的解释
Data Distribution 数据分布	Assess and compare properties of distributions 评估及比较分布的特性	Assess and compare properties of distributions, such as: 评估及比较分布的特性，比如： 1) Where sample values are centered 数据中心值集中在什么位置 2) Whether a sample distribution is symmetrical or skewed 数据分布对称与否 3) Whether sample data follow a specific distribution 数据是否遵循特定分布规律 4) How many peaks exist in the sample distribution (more than one peak can indicate that data are from multiple populations) 数据分布中有几个峰形（多余一个峰形表明数据来源于多个数据群） 5) What the most commonly observed values in the sample are 最常见的数据	Distribution alone assumes the process is not shifting and gives no indication of time trends. 仅看分布假定工艺没有漂移，而且不能显现时间趋势
Individual Control Charts 单个控制图	Detect the presence of special causes 检测出存在特别原因	• Track the process level and detect the presence of special causes 跟踪工艺水平，发现特殊原因	Only detect subtle shift with rule sets that evaluate a series of points together. 只检测出与设定值微小漂移，与一系列点一起评估
Moving Range Control Charts 移动范围控制图	Track process variations 跟踪工艺变化	• Track the process variation and detect the presence of special causes 追踪工艺变化并且发现特殊原因	Range between successive points is a coarse estimate of process variability. 连续点之间的范围对工艺的变化只是粗糙的评估 Easy to do by hand or on the manufacturing line. 容易通过人工或在生产线操作
S Charts S 图	Track process variations 跟踪工艺变化	• Track the process variation and detect the presence of special causes 跟踪工艺变化，并且发现特殊原因 • Becomes preferred over the R chart when subgroup sample sizes reach 8-10. S chart is preferred for sample sizes>10. For smaller sample sizes the R and S chart give similar results. 当小组样品量达到 8-10 时，比 R 图更好。S 图适 用于样本量大于 10 的情况。对于小的样量，S 图和 R 图的结果相似。 • Should be used for variable sample sizes. 应使用不同样本量的情况。	Standard deviation is more robust than Range against extreme values and outliers in the sample. 针对样品中的极端值和异常值标准偏差比极差更稳健。 Best done with a calculator or computer. 最好采用计算器或计算机操作。
Histogram 直方图	Visualization of statistical anomalies 统计异常的可视化	• Show distribution 显示分布 • Examine the shape and spread of sample data 检查样品数据的排列和分布	Size of categories needs to be appropriate for the data 分组的大小应与数据相适应

Statistical tool 统计工具	Strength 优势	Purpose 目的	Awareness of statistical challenges 对统计挑战的认识
Process Capability 工艺能力	Performance evaluation 性能评估 Determine if it is capable, and that is meeting specification limits and producing "good" parts. (Process needs to be in control before assessing its capability; if it is not, then result will be incorrect estimates of process capability.) 判断是否工艺能力，以及满足标准限度，并且产生“好的”部分（在评估工艺能力之前要确保工艺处于受控状态，如果工艺不在受控状态，则评估结果是错误的）	• Continual improvement 持续改进 • Determine capability by comparing the width of the process variation with the width of the specification limits. 通过比较工序变化的范围和标准限度的范围来确定能力	Risk to over interpret statistical out of control as related to unacceptable product quality 过度解释与不可接受的产品质量相关的统计超出控制的风险
EWMA 指数加权移动平均	A type of time-weighted control chart that plots the exponentially weighted moving averages 一种时间加权类型的描绘指数加权移动平均的控制图	• Monitor in-control processes for detecting small shifts away from the target 为检测偏离目标的小的偏移提供控制过程的监控	Dampens variability of single events. Has a lag when displaying step changes. 忽略了单个事件的可变化性，当显示步骤变化的时候有延迟
CuSum Charts 累积和图表	Real time trend analysis A type of time-weighted control chart that displays the cumulative sums of the deviations of each sample value from the target value 实时的趋势分析一种时间加权类型的显示每个样品值与目标值的偏差的累积和的控制图	• Early warning on selected CQA/CPP 对选定的 CQA/CPP 的预警 • For detecting small shifts away from the target 用于检测对目标的微小偏离 • Pinpointing the particular time when a small shift occurred 当微小偏移发生时精确指出特殊时间	Risk to over interpret statistical out of control or a discernible mean shift as related to product quality 过度解释与产品质量相关的统计超出控制或一个确定的均值漂移的风险

3.1 Run Charts 运行图

Run Charts are a simple visual monitoring method. Data or statistics calculated from measurements are plotted on a chart in "time-order," as in **Figure 3.1-1** Technical details can be found in **Section 5.1.**
运行图只是简单的可监控方法。数据或经统计学处理的数据以时间顺序画在图上，如图 3.1-1 所示。技术细节可在 5.1 章节找到。

Figure 3.1-1 Run Chart 运行图



纵坐标：质量属性 横坐标：批次（按生产日期）

3.1.1 Typical Applications 典型应用

Run charts should be the first tool applied for monitoring all data in sequence. Once a reasonable number of data points are collected, and the distribution of the data is reviewed (see section 3.5 on histogram), the run chart may be converted into one of the other control charts below.
运行图是按顺序监控所有数据的首要方法。一旦一定量数据采集到后，可以回顾数据的分布（见 3.5 节），运行图可转换成以下其他类型的控制图。

3.1.2 Pros 优势

- Simple to create 容易创建
- Easy to visually identify general patterns in the data 容易看出数据的大致分布
- Do not assume a distribution 不能假定一种分布

3.1.3 Cons 劣势

- Variability is not considered in assessing process control 在评估工艺控制中不考虑变量

3.2 Control Charts: Individuals 控制图：单值

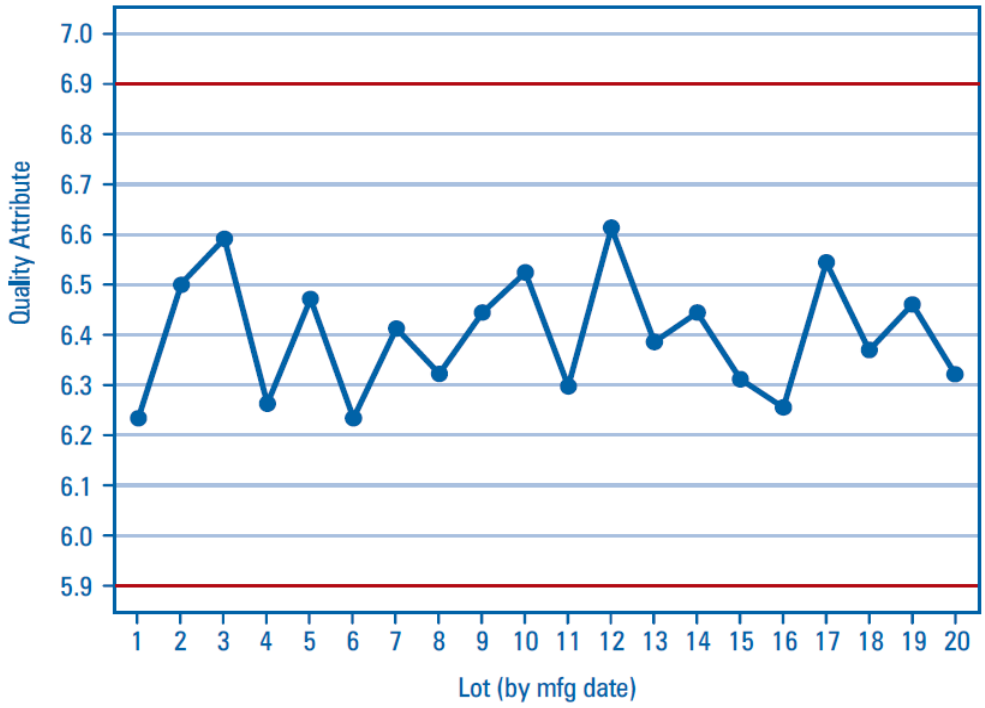
Individual Charts (I Charts) are used when only single, or individual, numeric measurements are used to evaluate a Quality Attribute (see **Figure 3.2.1-1).** The I Chart should be used in tandem with the Moving Range Chart described in **Section 3.3.** If the variability of a Quality Attribute is not in a state of statistical control, the value of an I Chart is questionable. Technical details can be found in **Section 5.2.**
单值控制图图（I 图）在只有一种或单个数字测量结果用于评估质量属性的时候使用（见图 3.2.1-1）。I 图应与 3.3 节中移动范围图串联。如果质量属性中的变量不在统计学控制状态下，I 图中的数值是令人怀疑的。技术细节见 5.2 节。

3.2.1 Attribute Control Charts 属性控制图

Attribute charts can be used for data that represent counts or proportions of a classification as opposed to measurements. A common application is evaluating multiple instances of conformance tests applied to elements within a group (e.g., 12 of 30 units that are nonconforming or a nonconforming proportion of 40%). Because the counts or proportions of these types of measures generally exhibit a non-normal distribution, different methods need to be used to establish limits. The generation of control charts based on non-normal distributions such as the "c chart" (for counts) or the "p chart" (for proportions) is outside of the scope of this document.

属性图可用于代表数量或分类的比例，与测量结果相反。一种常用是评估合规性监测的多种情况应用于组内各元素（例如：30 单元中的 12 个不合规或者说不合规率为 40%）。由于数量或比例通常为非正态分布，应用不同的方法建立限度。控制图的产生基于非正态分布如“C 图”（用于数量）或“P 图”（用于比例）在这份文件的范围之外。

Figure 3.2.1-1 Individual Control Chart 单值控制图



纵坐标：质量属性 横坐标：批次（按生产日期）

3.2.2 Typical Applications 典型应用

The Run Chart above is an individuals chart before adding control limits. An I Chart is used to monitor attributes where there is a single numeric measurement for each lot.

在增加控制限之前运行图就是个体图。I 图用于监控属性，当每一批有一个测量值的时候。

3.2.3 Pros 优势

- Simple to create 容易创建
- Easy to visually identify general patterns in the data 容易看出数据的大致分布
- Variability is considered in assessing process control 在评估工艺控制中考虑变量

3.2.4 Cons 劣势

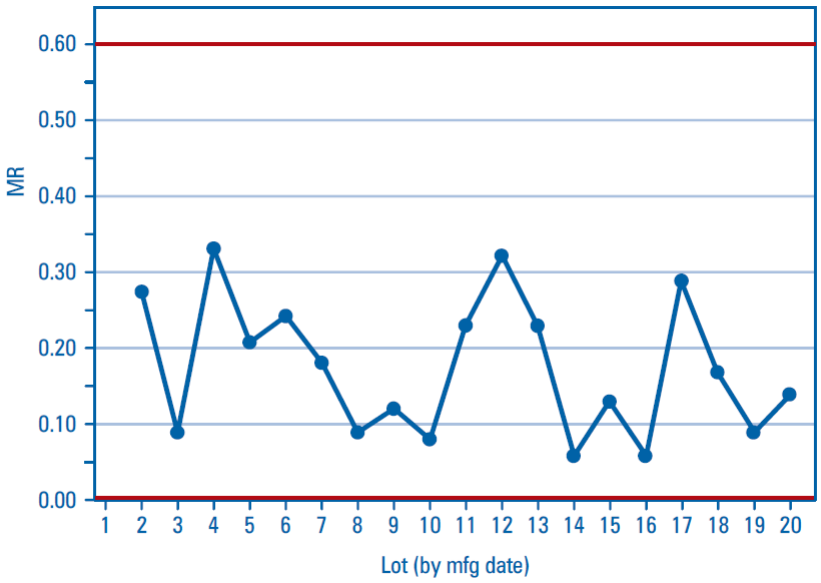
- Variability is based only on the change between individual data values potentially captured from each lot. That variability may include multiple sources.
  变量只基于单个数据体现的变化，偶然间从每批中发现的。这种变量或许有多个来源。

3.3 Moving Range Control Charts 移动极差控制图

Moving Range (MR) Charts as shown below in **Figure 3.3-1** (also called 'moving average charts'), are used in combination with an I Chart to evaluate the variability of a Quality Attribute. Technical details can be found in **Section 5.3.**

移动极差图见图 3.3-1（也称为“移动平均图”），与 I 图联合使用，评估质量属性的变化。技术细节见 5.3 节。

Figure 3.3-1 Moving Range Control Chart 移动极差控制图



3.3.1 Typical Applications 典型应用

The MR Chart is essentially an I Chart for monitoring the variability of a Quality Attribute. Although this chart is sometimes omitted, it should be used in tandem with the I Chart. If the variability of a Quality Attribute is not in a state of statistical control, the value of an I Chart is questionable.

MR 图实际上是一个 I 图，用于监控质量属性的变化。尽管这种图有时候被疏忽了，它应该与 I 图串联使用。如果一个质量属性的变化不在统计学控制范围内，I 图的数据是令人怀疑的。

3.3.2 Pros 优势

- Simple to create 容易创建
- Easy to visually identify general patterns in the data 容易看出数据的大致分布
- Variability is considered in assessing process control 在评估工艺控制中考虑变量

3.3.3 Cons 劣势

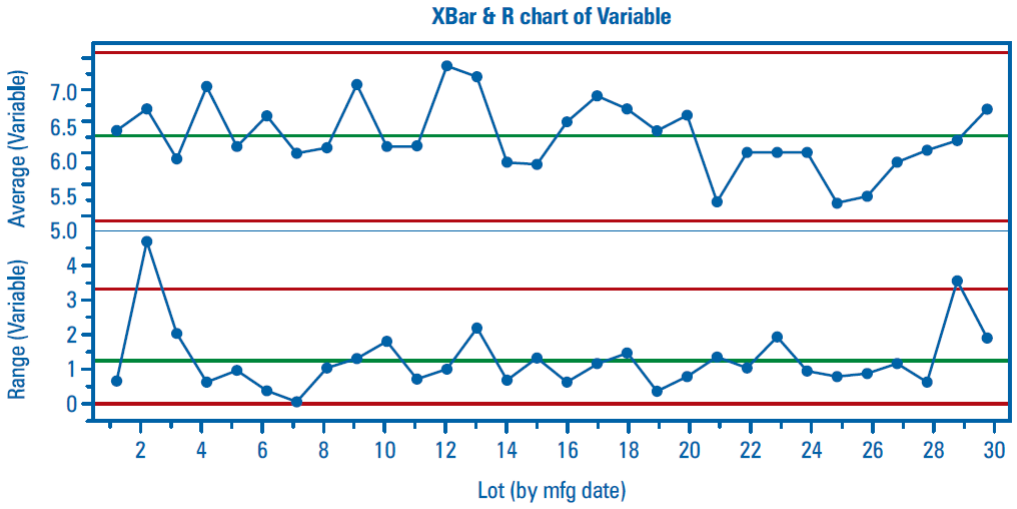
- Variability is based only on the change between individual data values potentially captured from each lot. That variability may include multiple sources.
  变量只基于单个数据见的变化，偶然间从每批中发现的。这种变量或许有多个来源。

3.4 Average and Variability Charts 均值图和变异性图

These charts are used to monitor the averages of small sets of data. Average and range charts take advantage of the Central Limit Theorem, which states that average results will tend to be normally distributed, regardless of the parent distribution. Of course, the larger the sample set, the greater the state of normality. The range of results within each data set is used to estimate overall variability. The **difference** *between* the sample average and the overall average is compared to the average range of results *within* each sample to assess statistical control. Variability is plotted on a separate chart.
这类图用于监控小组数据的平均值。平均和范围图利用了中心极限定理的优势，讲的是平均值应趋向于正态分布，与母体分布无关。当然，样本量越大，越显现正态分布。每组数据的范围用于评估整体变化。样本平均值与整体平均值之间的差异与每个数据的平均变化进行比较以评估统计学控制。变化在单独一张图上划出来。

Process variability can be monitored by either a Range chart (R chart) or the standard deviation chart (S chart). If the Variability Chart **(Figure** 3**.4-1)** indicates a statistically out of control situation, the Average Chart may not be meaningful. Technical details can be found in **Section 5.4.**
工艺变化可通过范围图（R 图）或标准偏差图（S 图）来评估。如果变化图（图 3.4-1）显示超出统计学控制的情况，平均图可能没有意义。技术细节见 5.4 节。

Figure 3.4-1 Average and Range Chart 均值图和变异性图



3.4.1 Typical Applications 典型应用

Average and Range charts are used in a wide range of applications.
均值和极差图有广泛的应用。

3.4.2 Pros 优势

- Simple to create 容易创建
- Lessens concerns about non-normal data 较少考虑非正态数据
- Easy to identify general patterns in the data 容易看出数据的大致分布
- Variability is considered in assessing process control 在评价工艺控制时，考虑到了变异性

3.4.3 Cons 劣势

Variability is based only on the change between individual data values potentially captured from each lot. That variability may include multiple sources.
变异性仅仅基于可能是从每批收集到的单个数据值之间的变化。而这一变异性可能包括多个来源。

If there are enough "within" batch samples to estimate standard deviation, the trend of these deviations on an S chart can be a better measure of change in variability than moving range charts.
如果有足够的批内数据，在 S 图上观察到的趋势可能比移动范围图上观察到的趋势更明显。

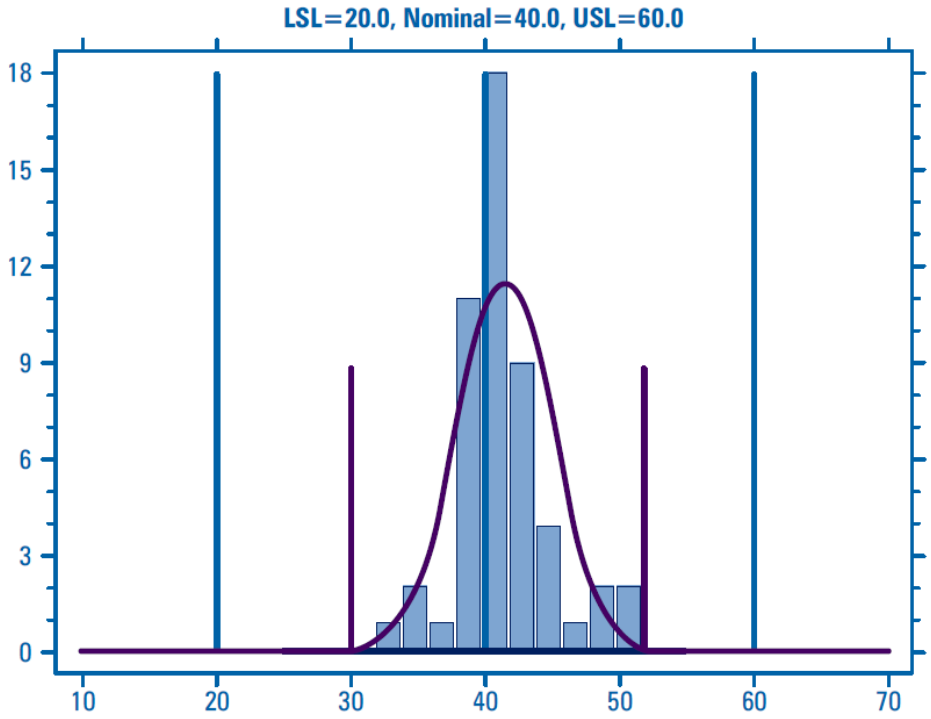
3.5 Histograms 柱状图

A histogram is a graphical representation showing how often each value in a set of data occurs. A histogram is used to understand the distribution of a data set by graphing rectangles to represent the count of observations in a data set over the class intervals. The height of the rectangles is equal to the number of observations in that class. The histogram, or distribution graph, is often an early technique to be applied in analyzing a data set and may aid in the selection of statistical techniques for further analysis.
柱状图是是一种表现一组数据发生几率的图。一个柱状图用于解释一组数据的分布，通过画方框来表现计数的观察在一组数据中一类间隔。方框的高度与该类观察的数量相等。柱状图，或称为分布图，通常是早期的技术，被应用于分析一组数据，可帮助筛选统计工具用于进一步的分析。

This method is useful in analyzing processes to understand the distribution of process outputs. This can be used to monitor changes to processes as well as variations from one time period to another by comparing multiple histograms. The method is also valuable as an initial exploration of a data set in order to better understand data and infer the distribution of the entire population.
这个方法在分析过程中是有用的，利于理解工艺输出的分布。这可以用于监控工艺的变化，以及一段时间与另一段时间的变化，通过对比多个柱状图。这个方法还可作为初始的探索一组数据以更好理解数据，以及推断整个数据的分布。

The histogram may also be plotted using a relative frequency distribution in which the number of observations in each class is divided by the total number of observations **(Figure 3.5-1).** In this case, the vertical axis will be the percentage and the rectangles will represent a percentage of the total data set for each class interval. Technical details can be found in **Section 5.5.**
柱状图可以采用相对频率分布来作图，每类观察的数量用总的观察数量来除（图 3.5-1）。在这种情况下，纵坐标是百分数，方框是整个数据的百分比。技术细节见 5.5。

Figure 3.5-1 Example of a Typical Histogram Showing Data Location in Relation To Specification Limits
显示数据位置对标准限度的典型直方图的示例



Several different characteristics can be observed from a histogram.
能够从直方图上观察到几个不同的特征。

3.5.1 Typical Application 典型应用

This method is useful in analyzing discrete and continuous data sets. It is an important early step in analyzing a data set or distribution.
这个方法用于分析离散的及连续的数据组。是分子一组数据或分布的早期应用阶段。

3.5.2 Pros 优势

This method allows visualization of where values fall on a measurement scale in relation to the frequency with which they occur. The histogram can summarize large data sets graphically.
这个方法允许观察数据在哪里掉到一个测量刻度上，与发生的频率相关。柱状图可用于总结大量数据。

3.5.3 Cons 劣势

Observation of a single histogram does not give any indication of any changes over time in the data points. For example, a process that is drifting may appear as a wider distribution, without a clear indication that a drift is underway.
单个柱状图不能给出任何随时间变化的信息。例如，一个工艺可能漂移，作为一个宽的分布，漂移的过程中没有清楚的显示。

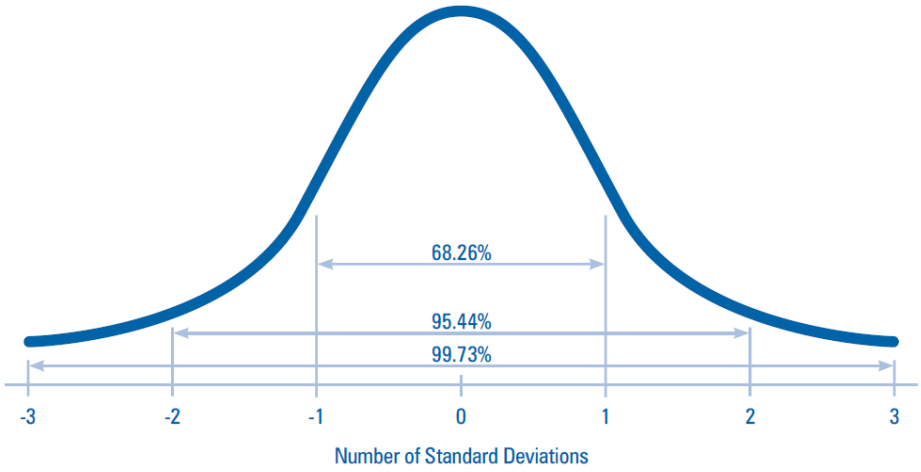
3.5.4 Distributions - Interpretation of Histograms 分布-柱状图的解释

The standard normal distribution is 1.0 where the distribution of values has been standardized so that the mean is 0.0 and the standard deviation is 1.0 (Figure 3.5.4-1). The following graph provides the theoretical percentage of results that fall between + 1, + 2 and + 3 standard deviations around the mean of 0:0.

正态分布是 1.0，数值的分布被标准化，因此平均值是 0.0，标准偏差是 1.0（图 3.5.4-1）。下列图提供结果的理论百分比，落在±1，±2，±3 标准偏差在平均值 0.0 范围。

Perfectly normal distributions are not found in actual practice. The percentages shown are only approximate for an actual data set or distribution.
完美的正态分布在实际中是不存在的。显示的百分数只是真实数据或分布的大概值。

Figure 3.5.4-1 Normal Distribution 正态分布

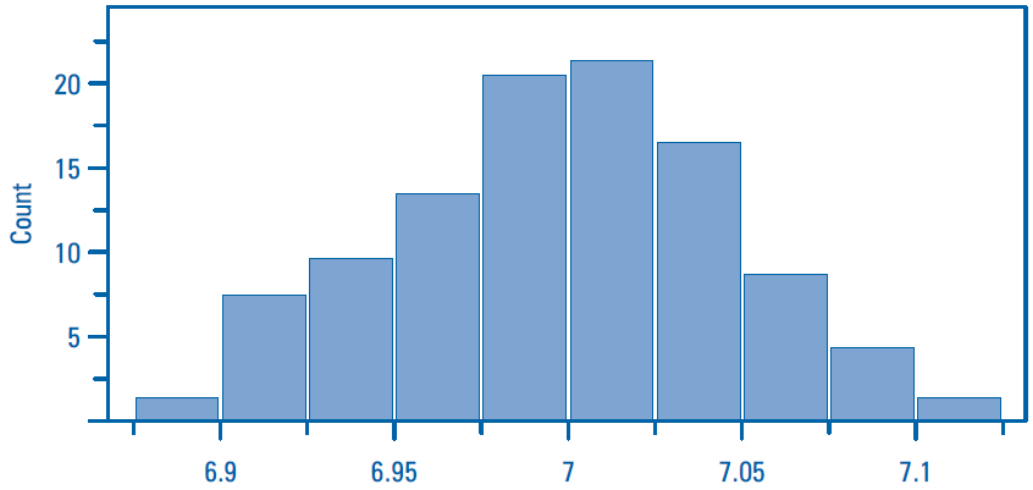


In the case of a normal distribution, the counts of data points are equally distributed around the mean or average value and have a specific contour. The assumption of approximate normality is common for data monitored with many of the charts presented here. In theory, when the data are normally distributed, 99.73% of results are expected to fall with ± 3 standard deviations of the mean. The 3 standard deviations in one direction represent a probability limit of 0.00135, or in both directions 0.0027, that a value will fall outside these limits by chance alone. For example, control limits set at these ranges would rarely (in this case = 3 out of 1000) falsely annunciate a point as out-of-statistical control limits, when the process performance remained typical. This reasoning of a probability limit can be expanded to non-normal distributions, such as the Poisson or the binomial distribution of attribute data (P, nP charts) with the appropriate mean and variance, and to more powerful statistical tools such as Prediction and Tolerance Intervals. The choices used for control limits should be based on a balance of the risk implications of failing to detect a real difference (limits are too wide), and falsely detecting a difference that isn't there (limits are too tight).
在正态分布的情况下，数据点的个数等量分布在平均值的周围，并且有一个特殊的等高线。假设的大概的正态是常见的用于监控数据在这里展现的图中。理论上讲，当数据是正态分布的时候，99.73%的结果会期望落在±3 标砖偏差的范围内。这 3 个标准偏差在一个方向代表发生的概率为 0.00135，两个方向为 0.0027，落在这些数据外的值是偶然发生的。例如，控制限设置在这些范围将很少（即千分之三）失败地预告一个点超出统计学控制范围之外，当工艺运行保持在典型状态。概率限度的原因可用于扩大到非正态分布，例如泊松分布或二项分布（P,NP 图），有合适的平均值及变化，而且可以扩展到更加有力的统计学工具如预测和公差的间隔。这些选择用于控制限应该基于风险的评估，要能检测到真正的变化（限度太宽），以及失败地检测到并不存在的差异（限度太窄）。

The interpretation of the below graph **(Figure 3.5.4-2)** is that the data set is approximately normally distributed. It can infer that the population is approximately normally distributed and has a bell-shaped curve.

下图的解释（图 3.5.4-2）是数据大概为正态分布。可以推断出大概呈正态分布，有一个铃铛形状的曲线。

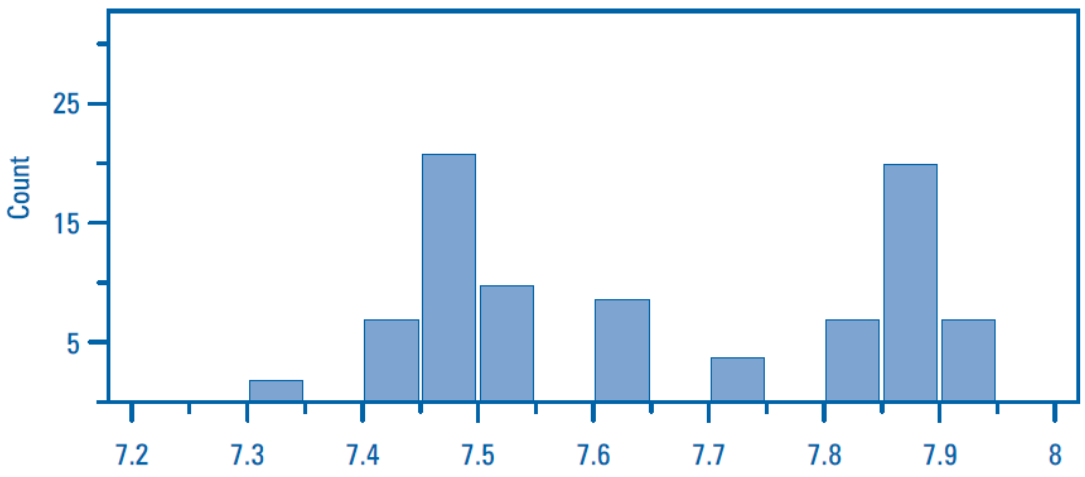
Figure 3.5.4-2 Histogram of a Normal Distribution 正态分布的柱状图



In case of a bimodal distribution, the data suggest that there may actually be two distinct populations in the data set, as in **Figure 3.5.4-3.** This could be as simple as the data were a measurement of the output from two systems. Further exploration of the data set is required in order to understand the nature of the variation in the sample set. Depending on the size and nature of the data set, there may be multiple modes or means within the data set.

在双峰分布的情况下，数据建议可能存在两组明显的数据，如图 3.5.4-3. 这可能是简单的，数据是两个系统的输出。有必要进一步探索数据组，以理解样本变异的性质。依赖于数据组的大小和性质，可能有多模型或数据组内的平均值。

Figure 3.5.4-3 Bimodal Distribution 双峰分布

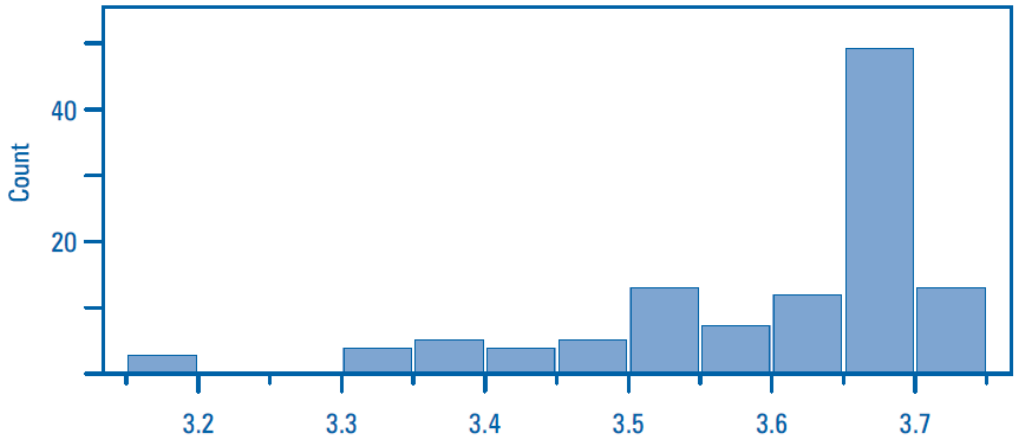


In case of a skewed distribution, the mean is skewed to one side of the distribution, as in **Figure 3.5.4-4.**

偏态分布情况下，平均值偏向一边，如图 3.5.4-4

This type of distribution is sometimes encountered when a system is unable to vary in one area or side of the range (constrained), but remains able to vary in another area or side of the range.
这类的分布有时候会遇到，当一个系统不能在一个区域变化或一边变化（约束），但是仍然能够在另一区域或范围的一边变化

Figure 3.5.4-4 Left Skewed Distribution



3.5.5 Hints for Use 使用注意事项

The histogram provides an overview of the distribution of a data set. It can be performed manually with graph paper or generated quickly using basic spreadsheet or statistical programs. After initial generation of the histogram, it is useful to plot the specifications of process output on the graph to get a rough visual estimate of the capability of the process.2
上述柱状图提供了针对对特定数据集的概貌。可以通过图表手动计算得到或者通过基础电子数据表或者统计程序便捷的生成。完成初步柱状图可以方便地在图表上绘制工艺输出的参数，从而得到工艺能力粗略的直观评价。

After generating the histogram, it is important to explore any variation from a visually normal distribution. Changes to the shape of the distribution can be caused by natural limits or by the grouping of several different populations. Potential differences from normality should be understood prior to use of a "standard" deviation to calculate ranges. After a review and understanding of the histogram, the data can be explored by more sophisticated techniques.
在完成柱状图的绘制后，有必要研究任何和直观常规分布所不同的差异。分布形态的变化可能是由内在的限制或者几个不同群体的分组造成的。在使用“标准”偏差计算范围之前应当理解和正态分布之间的潜在不同。在对柱状图进行审查和研究之后，这些数据还可以使用更为复杂的技术进行分析。

3.6 Process Capability (Cpk, Ppk) 工艺能力（C_{pk}，P_{pk}）

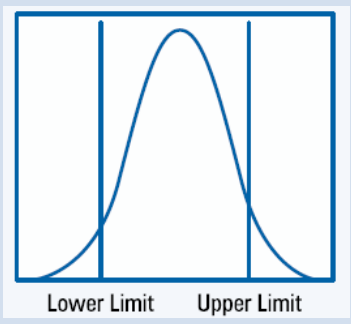
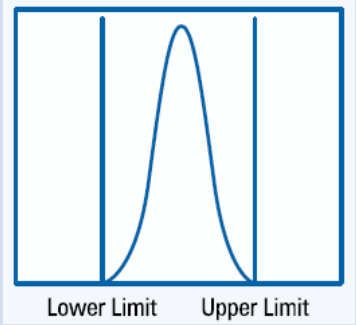
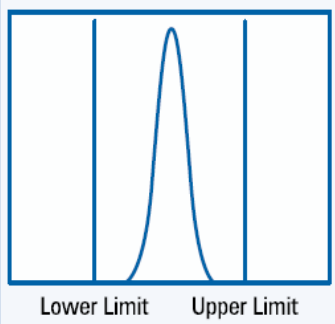
This section illustrates the calculation of the process capability indices Cp k and Pp k . These indices are defined as the ratios of the specification range to the natural variability of the data. They answer the question: *"Is this process capable of meeting its limits now or in the future?"* The variability in the data, which is compared to the limits, can be based on an estimate of the process variability. The variability is expressed as the average within the group variability (Cp k) or as the variability of the observed points, often expressed as the standard deviation of all data (Pp k). It is worth noting that for a process which is

statistically in control, Pp k is essentially equal to Cp k . Graphical examples of the relationship between variability and limits are illustrated in **Table 3.6.1-1.** Technical details can be found in **Section 5.6.**
本章介绍工艺能力的计算（C_{pk} 或者 P_{pk} 指数）。它是参数范围和数据自然变异性的比值。它回答了这样的问题：“这个工艺现在和将来可以满足它的限度吗？”。数据的变异性，相对于限度而言，可以基于对工艺变异性的评估而定。变异性可以表示成组内变异性 C_{pk} 的平均数或者所观察点的变异性，通常表示成所有数据（P_{pk}）的标准差。需要注意的是，对于统计学上受控的工艺而言，P_{pk} 本质上等同于 C_{pk}。变异性和限度之间关系的图示在表 3.6.1-1 中已经介绍。其技术细节见第 5.6 节。

3.6.1 Assumptions 假设

The current specifications are realistic, relevant to the potential for product impact, and were established appropriately. The data are approximately normally distributed. The data collected are truly representative of the process and were obtained from an independent sample. Finally, measurement variability is small or a small percentage of the process variability. Use of the Cp k index requires that the process is in a state of statistical control, with consistent variability between groups.
现有的标准是真实的，且和产品影响有潜在相关性，并被适当地评估。数据基本服从正态分布。数据都能真正代表工艺，且从一个独立样本中获得。最后，测量变异性较小，或者仅是工艺变异性的较小一部分。使用 C_{pk} 指数需要工艺处于统计控制状态之下，这样组间变异性保持一致。

Table 3.6.1-1 Significance of Cp Cp 的显著性

Value of Cp Cp 值	**C_p=0.5**	**C_p=1**	**C_p=3**
Graphical view of a process at different values of Cp 不同 CP 值工艺图形			
Sigma value in the given limits 给定限度内的 σ	3σ（±1.5σ）	6σ（±3σ）	18σ（±9σ）
Statistical number of values outside	13.58%	0.27%	Really 0 接近 0

the limits 超出限度的统计数据的值			
Statistical number of values inside the limits 限度范围内统计数据的值	86.42%	99.73%	99.999999%
Result 结果	Process statistically expected to routinely make nonconforming product 统计学上预期工艺经常生产出不合格产品。	Process statistically unlikely to make non conforming product 统计学上认为工艺不可能生产出不合格产品。	

3.6.2 Typical Applications 典型应用

These indices are one tool for studying processes and comparing relative risk between various measures. The interpretation of capability index values is shown in **Table 3.6.2-1.** Process capability indices should be used with other techniques, such as histograms, run charts and control charts, to assess the process. They should not be used to accept or reject lots of a product.

这些指数是研究工艺过程和比较不同测量之间相对风险的一种工具。表 3.6.2-1 对能力指数进行了解释。工艺能力指数需要和其他技术共同使用，例如柱状图、运行控制图以及控制图表来评估工艺。这些工具不应用来接收或者拒绝某个产品的批次。

Table 3.6.2-1 Interpretation of Cp Regarding Limits Taken Cp 所取限度的解释

Value of Cp Cp 值	Result 结果	Comment 建议
Cp＜0.6	Process is statistically poorly capable for these limits 统计学上认为工艺无法满足这些限度	Remedy process to decrease failure rate: Assess process design, measurement systems, and limits as appropriate 使用弥补工艺来降低出错率： 评估工艺设计、测量系统和适当的限度。
Cp＜1.0	Process statistically modestly capable for these limits 统计学上认为工艺基本能够满足这些限度。	The variation is wide in relation to the limits. Occasional deviations can be expected from the process as is. Remedy as appropriate.

		和限度相关的变异较大。预计会偶然出现和现有工艺相应的偏差。使用适当的弥补措施。
Cp≥1	Warn limit of 1.0 1.0 的警告限度	Tolerance of 6 Sigma (99.7%) is achieved. 可以达到 6σ 公差
1.0≤Cp≤1.33	Process statistically capable, likely to pass specifications routinely. 统计学上认为工艺可行，能够持续通过标准。	
Cp≥1.33	Process statistically very capable 统计学上认为工艺非常可行。	
Cp≥3	Process is much better than needed to meet the limits 工艺比达到限度的要求要好很多	Consider if the limits are relevant to the process (product impact basis). It may be that a risk based review would indicate that the process is adequately controlled without ongoing measurement 如果限度和工艺相关(从产品影响的角度看)，一个基于风险的审核可能会显示该工艺在没有持续监测的情况下也能充分地得到控制。

3.6.3 Pros 优势

Because process capability indices are not based on any specific units, they can be used as a common basis to compare between processes or measurement types, and among manufacturing steps and products.
由于工艺能力指数不基于任何特定单位，因此它们可以作为一个通用平台在工艺或者测量类型及生产步骤和产品之间进行比较。

3.6.4 Cons 劣势

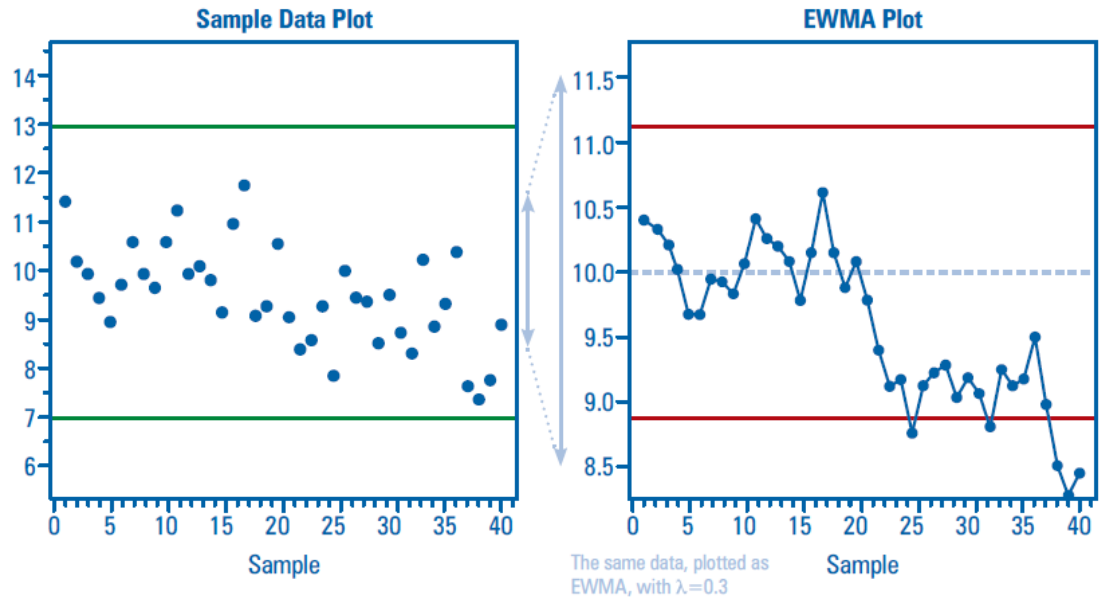
Observation of a single calculated capability index does not give any indication of change over time of the included data points. A process that is drifting may show a diminished capability, without clear indication that a drift is underway. For a precise estimate of capability, as with any summary statistic, considerations should be made for sample size using a lower confidence bound (as in ASTM E2281). With sample sizes less than 200 data points, consider comparing a tolerance interval of the process data to the specifications.
对于单个已得出的能力指数的观察无法看出所包含数据在整个时间段内变化的征兆。正在偏移的工艺可能表现出能力的下降，而没有明确的偏移正在进行的苗头。为了能够精确地对能力进行评估，结合使用汇总统计结果，应当注意样本量并使用更低的置信界限（如 ASTM E2281）。当样本量小于 200 个数据时，应当考虑将工艺数据的间隔公差和标准相比较。

3.7 **Exponentially Weighted Moving Average Charts** 指数加权移动平均控制图

Exponentially Weighted Moving Average (EWMA) charts are used to display the central tendency of a series of data points **(Figure 3.7-1).** The variability of individual values is dampened, allowing any underlying drift to be more easily observed. The weighted averaging favors the most recent data point, with prior points having a decreasing influence as distance increases. Technical details can be found in **Section 5.7.**

指数加权移动平均（EWMA）控制图表用于一系列数据的中心趋势（见图 3.7-1）。单个数据的变异性被抑制，以便任何潜在的偏移更为容易地被观察到。这种加权平均的方法更注重最近的数据，此前的数据会随着距离的增加而降低其产生的影响。技术细节见图 3.7-1 与 EWMA 图数据绘制的对比。

Figure 3.7-1 Data Plot Compared to EWMA Chart 与 EWMA 图数据绘制的对比



3.7.1 Typical Applications 典型应用

The EWMA chart may be used for variable or attribute data. This chart is able to highlight small changes in mean, but may not react as quickly to large changes or brief transient events. The net effect of the EWMA algorithm is the same as a first-order filter or dampening of individual values.

EWMA 图表可以用于变量或者属性数据的分析。该图表可以突出显示数值上微小的变化，但是不能很及时地反应大的变化或者十分迅速的事件。EWMA 算法的总体效果像是单个数据的初级滤器或者抑制器。

3.7.2 Pros 优点

The EWMA chart is useful for summarizing trends. It is also helpful for monitoring if a relatively noisy measurement system obscures the underlying process. This chart is also robust to non-normal data, due to the averaging across multiple points.

EWMA 图表便于得到总体趋势。如果一种相对杂乱的测量系统无法清晰地显示潜在的工艺的趋势，EWMA 图表也会有所帮助。这种图表还对非常规数据比较有效，这是因为该方法对多个数据进行了平均化。

As successive points are designed to influence each other, this chart will make common-cause variation more visually apparent.

由于连续的数据点注定会产生相互的影响，这种类型的图表会产生共因变异量。

This moving average may also be relevant for tracking key performance indicators, where the overall business outcome is dependent on the average result (e.g., production rates or yield).

该移动平均法可能也与关键性能的指示参数的追溯有关，商业总产量取决于平均结果（例如生产速率或收率）。

The EWMA chart is sensitive to small shifts in mean, and can display them with higher resolution than plotted raw data. The prompt detection of process mean changes can allow response to correct prior to a subsequent excursion. The CuSum chart (described in the following section) may be slightly more

powerful for annunciating mean shifts, but it is less intuitive to interpret. The EWMA chart has the comparative advantage of being in the same units as the measurement.
EWMA 图对平均值的微小变化敏感，以高于原始数据图的辨识率显示它们。工艺的快速检测意味着变化可以允许响应，以纠正先前及之后的偏离。累积和控制图（见下文）可能显示均值漂移方面稍强大，但解析方面不够直观。EWMA 图具有比较与检测结果相同单位的数据的优点。

3.7.3 Cons 缺点

The EWMA chart is not helpful for detecting changes in variability. This chart is designed such that the variability of individual points is reduced, so as to not distract from observation of the central trend of the data.
EWMA 图对于检测变异性中的变化没有帮助。该图被设计成减低单个数据点的变异性，以便不分散数据的集中趋势。

The dampening of the EWMA causes a lag in the response. The magnitude of a step change will only become apparent after a number of samples appear at the new average.
EWMA 的抑制导致响应滞后。一步变化的大小只会在许多样品出现新的均值后，才会变得直观。

Individual special cause events are not highlighted by the EWMA chart. Other means of detection of outlying individual results should be employed (e.g., alert/action limits, individuals chart, etc.).
单个特定事件不会在 EWMA 图表中得到强调。需要使用其他方法（如警戒/行动限，个体控制图表等）来检测独立结果的偏离。

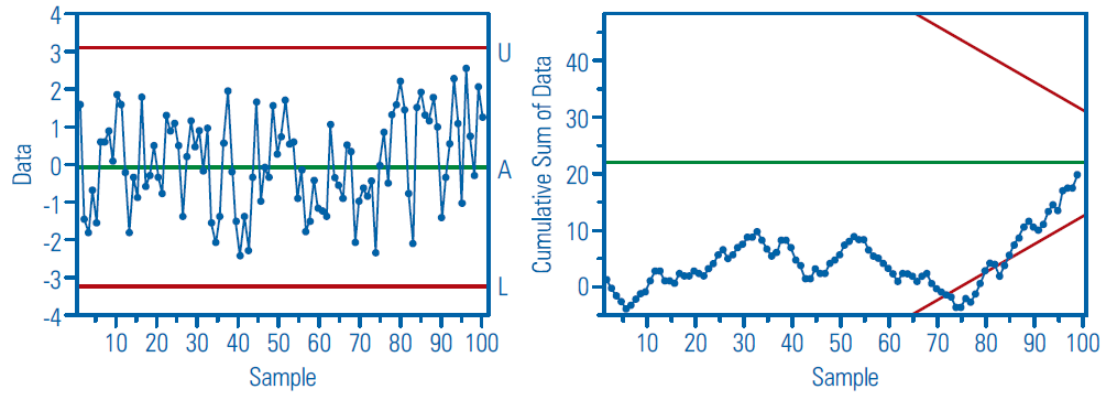
3.8 CuSum Charts 累积和图

Chart of the cumulative sum (CuSum) represents a quality control chart with a memory. As samples accumulate, these charts total the sum of the deviations from a given specification value.
累积和图（CuSum）代表这一种带有记忆的质量控制图表。随着样本的累积，这些图表会将给定标准值偏离量进行累积。

This approach is different than most other quality control charts (e.g., x-bar charts) that map individual results on a defined 'window' of ranges. On these charts, previous values are not taken into account when trying to detect unusual events.
这种方法和其他大多数质量控制图表（如 X-bar 图表）都有所不同，它是将单个结果绘制在制定的“窗口”中。在这些图表中，在试图检测非正常事件时，不考虑此前已经发生的数据。

The CuSum chart is the most sensitive for detecting changes in mean. It highlights changes in mean as a shift in slope (Figure 3.8-1). Technical details can be found in Section 5.8.
这种累积和图对于检测平均数的变化最为敏感。它可以以斜率的形式凸显出平均值的变化（图 3.8-1）。其技术细节见第 5.8 节。

Figure 3.8-1 Run Plot Compared to CuSum Chart of the Same Data



3.8.1 Process Features Suitable for This Type Method 适用于这种方法的工艺特征

CuSum charts should be implemented as a statistical tool at the shop floor, where processes must be monitored and guided.
累积和图只能在工艺受到监控和指导的车间中作为一种分析工具使用。

This method can be considered to use for all types of data recording, where an understanding of changes in the average is important. Such data could be taken from any monitored value, such as process parameters from in-line, at-line or off-line recording.
当对于平均数变化的认识很重要的情况下，这种方法被认为适用于所有类型的数据记录。这些数据可以来自于任何监控到的数据，如在线的、在位的或者离线记录的工艺参数。

3.8.2 Typical Applications 典型应用

Generally CuSum charts are used for the detection of anomalous behavior so they are implemented and typically used for:
累积河图常用于检测不正常的行为，所以典型地用于：

- Monitoring and detection of a change 监控和检测变化
- Identify changes in the probability distribution of a stochastic process 在随机工艺的概率分布中鉴定变化
- Taking the advantage to stop processes as soon as significant trends are observed 利用这种图表的优势，在发现显著的趋势时中断工艺过程

3.8.3 Pros 优势

The CuSum charts represent a sequential analysis technique. The sample size is not fixed in advance and the data are evaluated as they are collected. The early detection of a change in mean sometimes allows for the initiation of corrective actions at a much earlier stage at consequently lower costs.
累积和图代表了一种顺序分析方法。事前不固定样本量并且数据在采集时就进行了评估。这种针对平均值变化的检测有时会允许在较早的阶段触发纠错行动从而降低成本。

The location of the inflection point provides a valuable clue as to which time frame to review for potential changes.
趋势变化的地方可以提供一种宝贵的线索来提示进行需要进行审核的可能时间框架。

3.8.4 Cons 缺点

There is a potential for over-interpretation of the prompt detection of statistically significant differences as relevant to product impact. The presence of a discernible difference in mean does not imply that specifications have been exceeded. Consider the risk that CuSum charts provides an alert system with potential to overreact.

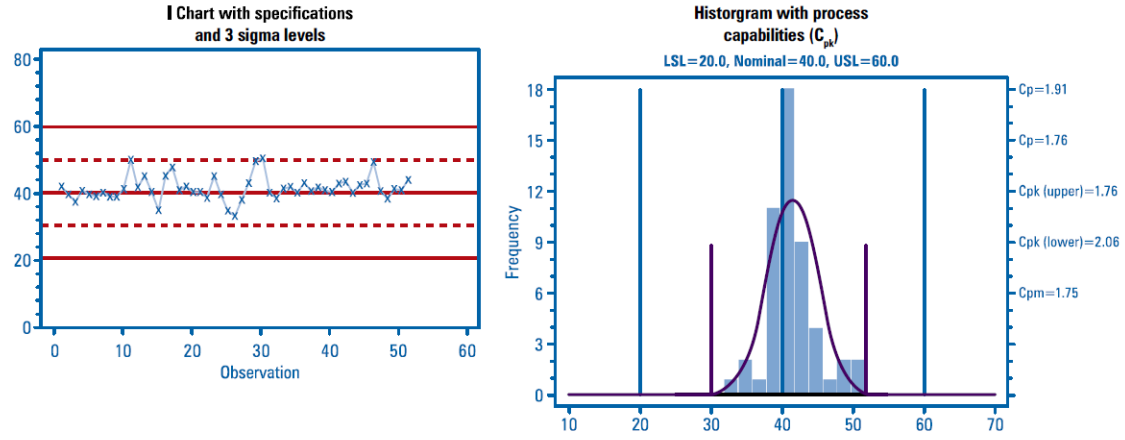
当涉及到对产品的影响时，这种方法对统计学上显著差异的迅速检测存在着潜在的过度解释的可能。平均值出现可检测的差异并不一定意味着已经超出了标准限度。应当注意累积和图提供的警戒系统存在着潜在的过度反应的风险。

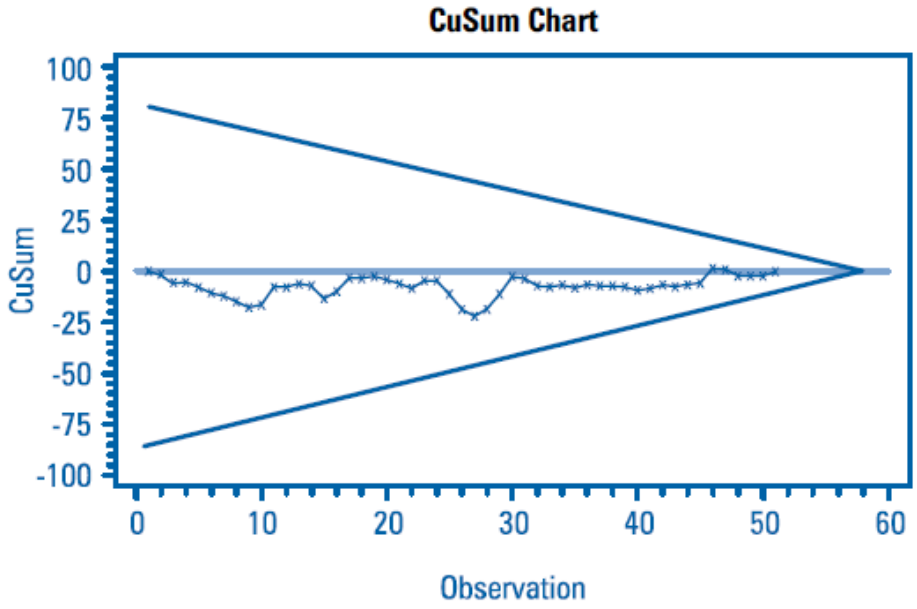
3.9 Examples of Efficient Mixture of the Statistical Toolbox 统计工具箱有效混合使用的实例

As an example, CuSum Charts have been used in a multi-product manufacturing facility of Active Pharmaceutical Ingredients (APIs). Many different products and conditions are manufactured e.g., larger campaigns with good knowledge of the manufacturing process and small campaigns with less historical data. The grouping of an x-bar chart, histogram and CuSum charts combined into the same display have been employed to efficiently convey process performance **(Figure 3.9-1).**

举例，累积和图曾用于多种原料药（API）的生产车间。许多不同的产品和条件用于生产，如对生产工艺有良好认知的大规模集中生产，又或者是缺少历史数据的小规模生产。一组整合了 X-bar 图表、柱状图表和累积和图到同一个图表的方法被用于有效地展示工艺性能（见图 3.9-1）

Figure 3.9-1 Example of a Tool Bar for Statistical Control of a Process 过程统计控制工具栏实例




CuSum Chart
100
75
50
25
0
-25
-50
-75
-100
CuSum
0
10
20
30
40
50
60
Observation

4.0 Acceptance Sampling 验收抽样

Acceptance sampling is the process of taking a representative sample from a lot, which may be composed of distinct individual units and then making a decision about the disposition of that lot. The sample is inspected (i.e., measured, examined or tested) and compared to the requirements. The decision is to reject or accept the lot, based on the conformance to specified quality levels of the number of defects detected in the sampled units. Defects are defined as a departure of quality characteristics from intended level. Technical details can be found in **Section 5.9.**

验收抽样是从一批中取出有代表性样品的过程。批可以由单独的个体单元组成并形成批处理的决定。样品被检查（如测量、检查或测试）并与要求比较。根据取样单元检测的缺陷数规定的质量水平的符合程度，决定批的拒接或接收。缺陷被定义为背离预期水平的质量特性。技术详情见第 5.9 节。

4.1 Typical Applications 典型应用

Acceptance sampling is used to decide whether or not the lots, on average, are likely to be acceptable. This will ensure against the release of highly defective lots as well as assure that the average quality going to customer is at or better than some specified level. Sampling will protect customers from exposure to high defect levels and reject obviously bad lots. Acceptance sampling is also often applied on incoming materials.

利用验收抽样决定批在一般情况下是否可以被接收。验收抽样可以保证高度缺陷批不被放行，同时确保客户获得的平均质量水平等同或更优于规定的质量水平。抽样检验可以使客户免于接触高缺陷水平产品并拒绝明显不合格批。验收抽样也用于进厂物料的检验。

A sampling approach may be appropriate for incoming material inspections, in-process components, and possibly finished goods inspections where 100% inspection is not required. Sampling can be applied across a supplier/customer junction or between steps or business sections within a company. Sampling may also be applied at line or in line as a part of ongoing monitoring during production. Sampling approaches are clearly required for unit attributes that can only be tested destructively. When sampling is considered, the costs of sampling should be balanced against the hazard presented by defective components. The selection of samples and subgroups that are required for consideration are as previously described in the prerequisites for data analysis in **Section 3.0**

抽样方法可以适用于进厂物料检查、中间产品检查和不需要 100%检查的成品检查。抽样可应用于供需双方的交接或用于公司内部业务部门或步骤之间。抽样也可以用于生产过程中持续监控的在线监测。对于只能破坏性测试的计数单元显然需要抽样方法。当考虑抽样时，抽样的成本应该与有缺陷的零部件所表现的危害相平衡。选择所需要考虑的样品和亚组的条件同先前在第 3 节中所描述的数据分析的先决条件。

4.2 Key Terms 关键术语

Sampling is a complex topic in it of itself and formal training is highly recommended. This document is only intended to provide an overview of general concepts to put sampling into context with other statistical tools. Further resources (e.g. , ANSI/ASQ Z1.4-2008: Sampling Procedures and Tables for Inspection by Attributes and/ or ANSI/ASQ Z1.9-2008: Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming) should be studied for further details or guidance in developing specific plan.[3]

抽样本身是个复杂的主题并高度推荐正式培训。本文仅用于提供一般概念的概述，把抽样置于其他统计工具之中。在开发具体抽样方案时应研究更多的资源以获得更多细节和指南（如：ANSI/ASQ Z1.4-2008:计数型检查抽样规程和抽样表和/或 ANSI/ASQ Z1.9-2008:按不合格百分比计量型检查抽样规程和抽样表）。[3]

4.2.1 Acceptable Quality Limit (AQL) 接收质量限(AQL)

The AQL represents the worst tolerable quality level in a continuous series of lots that can be considered to be acceptable as a process average by the customer. AQL-based sampling plans are designed to have a high probability of accepting lots at a given AQL.

AQL 代表在连续序列批中一个过程平均值可以被客户接受的最差容忍质量水平。基于 AQL 的抽样方案的设计在给定的 AQL 中接收批概率较高。

4.2.2 Rejectable Quality Level (RQL) 拒收质量水平(RQL)

Sometimes called Lot Tolerance Percent Defective (LTPD), Limiting Quality (LQ) or Unacceptable Quality Limit (UQL); it is the highest percentage of defective units in any individual lot before it is considered unacceptable by the customer. RQL-based sampling plans are designed to have a high probability of rejecting lots at a given RQL.

有时被称为批容限缺陷百分比（LTPD），极限质量（LQ）或不可接受质量限（UQL）。是指客户对不可接收的孤立批中单元产品缺陷的最高百分比。基于 RQL 的抽样方案的设计在给定的 RQL 中拒收批概率较高。

4.3 Types of Sampling 抽样类型

There are different sampling approaches can be applied to both attributes and variables.

有各种抽样方法可以用于计数检验和计量检验。

4.3.1 Attributes Sampling 计数型抽样

Attributes Sampling is used on discrete outcome type of data (go / no go gauge, missing parts in an assembly, individual units under / oversized). Count type of data (e.g., number of under- or over-filled tablets in a bottle) is also an attribute sampling. The attribute case is the most common for acceptance sampling.

计数型抽样是用于离散型结果的数据类型（合规 /不合规、装备中部件缺失、独立单元产品太小/超大）。计数型数据（如瓶子中片数不足或过多）也是计数型抽样。计数型抽样是最常用的接收抽样。

4.3.2 Variable Sampling 计量型抽样

When each sample is measured on a continuous scale, the sampling type is denoted as variable sampling. Examples might be weight, torque, potency, or moisture. The variable measurement provides much more information with a smaller sample size than attribute sampling. Variable sampling plans assume that the data is normally distributed.

如果样品是在一个连续范围内测量的，则抽样类型记为计量抽样。例子可以是重量、扭矩、效价、或水分。计量型测量使用较小样本量提供的信息比计数型抽样要大。计量型抽样方案假定数据服从正态分布。

4.4 Types of Acceptance Plans 接收方案类型

Different sampling plans can be used to balance test costs against complexity and risk of error.

可以使用不同的抽样方案使测试成本与复杂性和误差风险平衡。

4.4.1 Single Sampling Plans 单次抽样方案

One sample of items is selected at random from a lot and the disposition of the lot is determined from the resulting information. These plans are usually denoted as (n, c) plans for a sample size n, where the lot is rejected if there are more than c defectives. These are the most common, and easiest, plans to use, although not the most efficient in terms of average number of samples needed. There are two widely used ways of picking (n, c):

随机从一批产品中 选择一个项目的样品并根据信息结果处理该批产品。这个方案对样品量为 n 的通常表示为（n, c），如果缺陷大于 c 则拒收该批产品。这些是最常用、最简单的使用方案，但在所需样品的平均数方面并不是最有效的。有两种广泛使用的选择方式（n, c）：

- Use tables (Standards) that focus on either the desired AQL or the RQL (LTPD)
  利用 AQL 或 RQL（LTPD）的表格（标准）；

- Specify two desired points on the Operation Characteristics (OC) curve and solve for the (n, c) that uniquely determines an OC curve going through these points.
  在操作特性曲线（OC）上指定两个点，确定唯一一条 OC 曲线通过这些点求解（n, c）。

4.4.2 Double Sampling Plans 二次抽样方案

After the first sample is tested/inspected, there are three possibilities:

第一次样品测试/检查后，有三种可能：

1. Accept the lot 验收批
2. Reject the lot 拒收批
3. No decision (extend samples) 无结果（扩展样品）

If the outcome is (3), a second sample is taken. The procedure is to combine the results from both samples and make a final decision based on the information.

如果结果是（3），则取第二个样品。程序是结合两个样品的结果形成最终结论。

4.4.3 Individual Sampling Plan 单独取样方案

A specific plan is the sample size and the accept/reject numbers.

具体方案是样品量和验收/拒收数。

4.4.4 Sampling Scheme 抽样方案设计

A sampling scheme consists of a normal sampling plan, a tightened sampling plan, a reduced sampling plan, discontinuation and rules for switching from one to the other.

一个抽样方案包括正常抽样方案，加严抽样方案，减量抽样方案，停止和一个方案转到另一方案的规则。

4.5 Pros and Cons 优缺点

Sampling is a means of adjudicating quality at a certain step. When properly applied, it allows a likelihood-based discussion of measurement costs and risk trade-offs to be made at a specific process juncture. This also allows a rational basis when deciding on appropriate levels of destructive testing.

抽样是在一定步骤上评判质量的一种手段。如果运用得当，它允许基于可能性的讨论测量的成本和风险在一个特定的过程交接点的取舍。这也使得在决定适当水平的破坏性试验时具有一个理性的基础。

Acceptance sampling is not a means of assuring defect-free outcome. It does not assure an exact quality level is present, as all detections of intermittent events are based on likelihoods, and there is inherent randomness to any particular detection outcome. The value of acceptance sampling is as an independent guard against the catastrophic failure of the testing of in-process materials and drug products. It monitors the output and validates the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products. Acceptance sampling may be costly both in terms of materials and time. It should not be used as an alternative to process monitoring and improvement.

接收抽样不是确保无缺陷结果的一种方法。它并不能保证是否有一个确切的质量水平，因为间歇性事件的所有检测是基于似然性上的，所有对任何特定的检测结果都有固有的随机性。接收抽样的价值是作为一个独立的防范中间物料和药品灾难性故障的测试。接收抽样监控输出并确认可以导致中间物料和药品特性变异的制造工艺参数。接收抽样在材料和时间两方面可能是昂贵的。它不应该被用来作为过程监控和改进的一种替代方法。

3： Much has also been written outside of the pharmaceutical industry on selecting sample sizes, for further discussion also see ASTM E2587 “Use of Control Charts in Statistical Process Control”, ASTM E2881-08a “Standard Practice for Process and Measurement Capability Indices”, ASTM E2709-09 “Standard Practice for Demonstrating Capability to Comply with a Lot Acceptance Procedure”, or other statistics texts as appropriate.

3：关于样本量的选择，医药行业之外有很多指南，进一步的讨论也可以阅读 ASTM E2587 “Use of Control Charts in Statistical Process Control”, ASTM E2881-08a “Standard Practice for Process and Measurement Capability Indices”, ASTM E2709-09 “Standard Practice for Demonstrating Capability to Comply with a Lot Acceptance Procedure”或其他适宜的统计学课程。

5.0 Appendices: Technical Details and Examples 附件：技术细节和实例

These appendices relate to the previous sections on statistical tools. Each section in the body of the text above has a corresponding section in these appendices, which provides technical details along with examples.
这些附件与前面几个章节的统计工具有关。在之前文本的每一章节都有相应的部分在这些附件中，这些附件提供技术细节连同一些实例。

5.1 Run Charts 运行图

The following detailed instructions include a step-by-step method for calculating initial control limits as a process and then refining them as more data become available and the process becomes routine. This illustrates one particular approach using the moving range; other approaches such as multiple of standard deviations (sigma) and choices for numbers of lots to incorporate in averages are valid as well and may be employed at the user's discretion.
以下细节说明包括计算工艺起始控制限度的方法，通过大量有效的数据精炼控制限度，使工艺变得程序化。举例说明了使用移动极差的详细方法。其他方法如标准偏差（西格玛）的倍数以及通过选择多批次计算平均值同样也是有效的。

5.1.1 Technical Details 技术细节

Step 1 — Place data or statistics in time-order.
第一步—列出数据或按时间顺序统计。

Step 2 — Create a plot of the data with the range of data values on the dependent vertical axis and the timing of the data on the independent horizontal axis. The plot should be created as soon as the first datum value is available.
第二步—用这些数据绘制一个图，用数据值范围做纵轴，用数据的时间做横轴。第一个数据一有效就应该绘制图。

Step 3 — Connect plotted points with lines.
第三步—将这些点连成线

Step 4 — Add subsequent data values and connect to the previously plotted point as the data become available.
第四步—添加后续的数据值并且连接到先前绘制的点，使得这些数据变得有效。

5.1.2 Example 实例

Step 1 — Place data or statistics in time-order. The following data in Table 5.1.2-1 were collected from individual measurements of 20 independent lots. The lots are ordered by manufacturing date:
第一步—列出数据或按时间顺序统计。下面在表 5.1.2-1 中的数据是从 20 个独立批次单独测量收集的。这些批次是以生产日期为序的。
Table 5.1.2-1 Lot Data by Manufacture Date 以生产日期统计的批数据

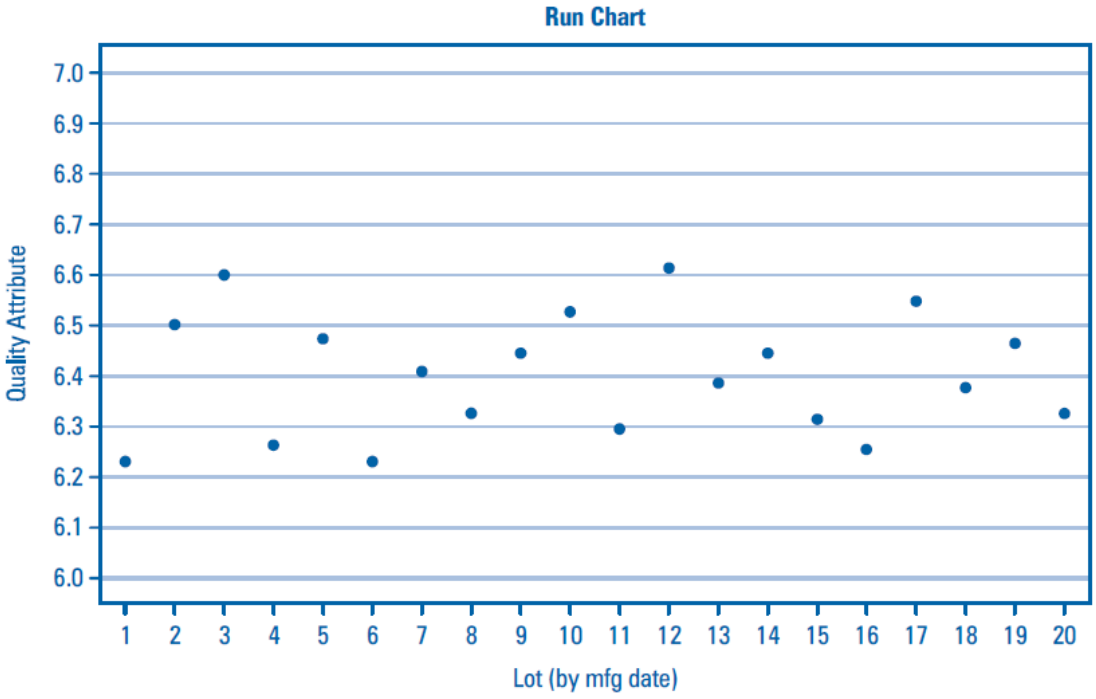
Lot	Quality Attribute
1	6.23
2	6.50
3	6.59
4	6.26
5	6.47
6	6.23
7	6.41
8	6.32
9	6.44
10	6.52

Lot	Quality Attribute
11	6.29
12	6.61
13	6.38
14	6.44
15	6.31
16	6.25
17	6.54
18	6.37
19	6.46
20	6.32

Step 2 — Create a plot of the data with the range of data values on the vertical axis and the timing of the data on the horizontal axis (Figure 5.1.2-1). The plot should be created as soon as the first value is available.

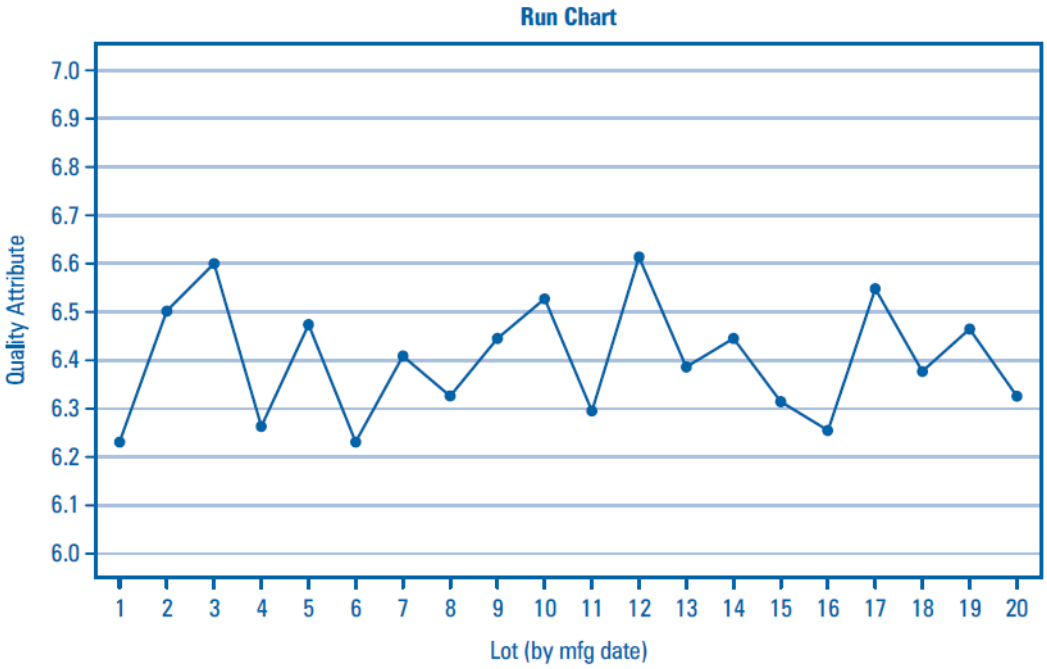
第二步—用这些数据绘制一个图，用数据值范围做纵轴，用数据的时间做横轴（图 5.1.2-1）。第一个数据一有效就应该绘制图。

Figure 5.1.2-1 Run Chart (Plot of Lot Data) 运行图（批数据绘点图）



Step 3 — Connect plotted points with lines as shown in Figure 5.1.2-2.
第三步—连接点成为线如图 5.1.2-2 中所示。

Figure 5.1.2-2 Run Chart 运行图



Step 4 — Add subsequent data values and connect to the previously plotted point as the data become available.
第四步—添加后续的数据值并且连接到先前绘制的点，使得这些数据变得有效。

5.2 Control Charts: Individuals 控制图表：单值

5.2.1 Technical Details技术细节

Step 1 — Place data or statistics in time-order
第一步—列出数据或按时间顺序统计

Step 2 — Create a plot of the data with the range of data values on the vertical axis and the timing of the data on the horizontal axis. The plot should be created as soon as the first datum value is available.
第二步用这些数据绘制一个图，用数据值范围做纵轴，用数据的时间做横轴。第一个数据一有效就应该绘制图。

Step 3 — Connect plotted points with lines.
第三步—将这些点连成线

Step 4 — Add subsequent data values and connect to the previously plotted point as the data become available.
第四步—添加后续的数据值并且连接到先前绘制的点，使得这些数据变得有效。

Step 5 — After 15 data points[4] are collected, compute the overall average of the data values ($\bar{X}$).

第五步—在收集 15 组数据点[4]后，计算全部数据的平均值（$\bar{X}$）

Step 6 — Add a line to the plot at the $\bar{X}$ value on the vertical axis.

第六步—在纵坐标上以$\bar{X}$值绘制一条直线

Step 7 — Compute the moving range (MR) for each consecutive pair[5]of data values by subtracting the lower value from the higher value. MR will always be a positive number.

第七步—计算每对连续数据的移动极差[5] (MR)，通过较高的减去较低的，移动极差将总是正数。

Step 8 — Compute the average of all MR values, ($\overline{MR}$)

第八步—计算所有移动极差的平均值($\overline{MR}$)。

Step 9 — Compute the Upper Control Limit (UCL) using the following formula: [6]

$$UCL = \bar{X} + 2.66 \times \overline{MR}$$

第九步—通过下面的公式[6]计算控制上限（UCL）

Step 10 — Compute the Lower Control Limit (LCL) using the following formula:6

$$LCL = \bar{X} - 2.66 \times \overline{MR}$$

第十步—通过下面的公式[6]计算控制下限（LCL）

Step 11 — Add UCL and LCL to the chart for monitoring data points 16-30. These limits should not be used retrospectively on prior data points

第十一步—在图中添加 UCL 和 LCL 用来监控 16-30 的数据点。这些接线不能用来对之前的数据点进行回顾

Step 12 — After 30 data points are collected, re-compute Upper and Lower Control Limits

第十二步—在收集 30 个数据点后，重新计算上下控制线

Step 13 — Adjust UCL and LCL to the chart for monitoring points 31 +

第十三步—在图上调整上控制线和下控制线用于监控 31+后的点。

Step 14 — If any data point falls outside a control limit, investigate the root cause. If the deviation can be assigned to a "special" cause, correct the cause. If the deviation cannot be assigned to a special cause, evaluate the impact prior to continuing. When a special cause can be assigned to a deviation, that data point should continue to be included on the chart. But it should be excluded from calculations of the average, UCL and LCL.

第十四步—如果任何数据点落在一个控制线以外，调查其根本原因。如果这个偏差能被指定为一个“个别”原因，纠正这个原因。如果这个偏差不能够指定为一个特别的原因，在继续进行前评估这个影响。当这个个别原因被指定为一偏差时，控制图中仍需包括这个数据点。但是它应该被排除在平均值，UCL 和 LCL 计算之外。

4. It is typical to review an initial set of data against expectations from validation or development, and then to establish the initial working control limits on first series of commercial production. This isthen revisited as a broader set of data become available
   它是典型审查最初一组数据与预期验证或开发违背的，然后在第一批商业化产品建立最初的工作控制线。然后重新变为有效的更广泛的数据。

5. MR may be computed using a "run" of data longer than two consecutive points, but that is a more advanced discussion
   MR 可以利用“运行”计算数据长度大于 2 个连续点，但是一个更先进的讨论。
6. The multiplier of 2.66 is directly related to the use of two consecutive data points, or a run length of two and the assumption that 3SD limits are employed
   2.66 是连续两个数据点的倍数，或预设的长度为 2 并且假设使用 3 倍的标准偏差限。

5.2.2 Example 实例

The first 15 data points represent the first fifteen lots in time-order:
最早的 15 个数据点代表按照时间顺序的最早的 15 批次。

Step 1 — Place data or statistics in time-order.
第一步—列出数据或按时间顺序统计

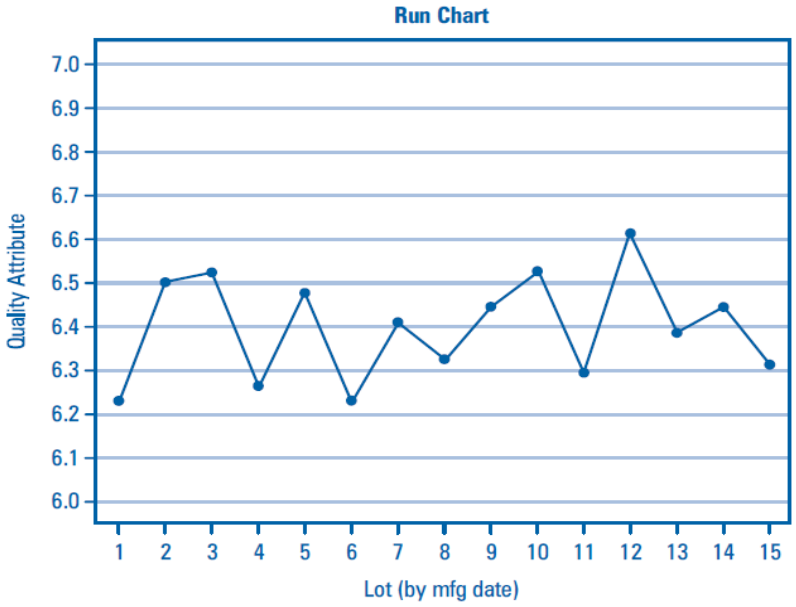
Table 5.2.2-1 First 15 Data Points/ Lots 最早的 15 个数据点/批次

Lot	Quality Attribute
1	6.23
2	6.50
3	6.59
4	6.26
5	6.47
6	6.23
7	6.41
8	6.32
9	6.44
10	6.52
11	6.29
12	6.61
13	6.38
14	6.44
15	6.31

Step 2 — Create a plot of the data with the range of data values on the vertical axis and the timing of the data on the horizontal axis. The plot should be created as soon as the first data value is available
第二步—用这些数据绘制一个图，用数据值范围做纵坐标，用数据的时间做横坐标。第一个数据一有效就应该绘制图。

Step 3 — Connect plotted points with lines
第三步—将这些点连成线

Figure 5.2.2-1 Run Chart (Plot of Lot Data) 运行图（批数据绘点图）



Step 4 — Add subsequent data values and connect to the previously plotted point as the data become available

第四步—添加后续的数据值并且连接到先前绘制的点，使得这些数据变得有效。

Step 5 — After 15 data points are collected, compute the overall average of the data values ($\bar{X}$))

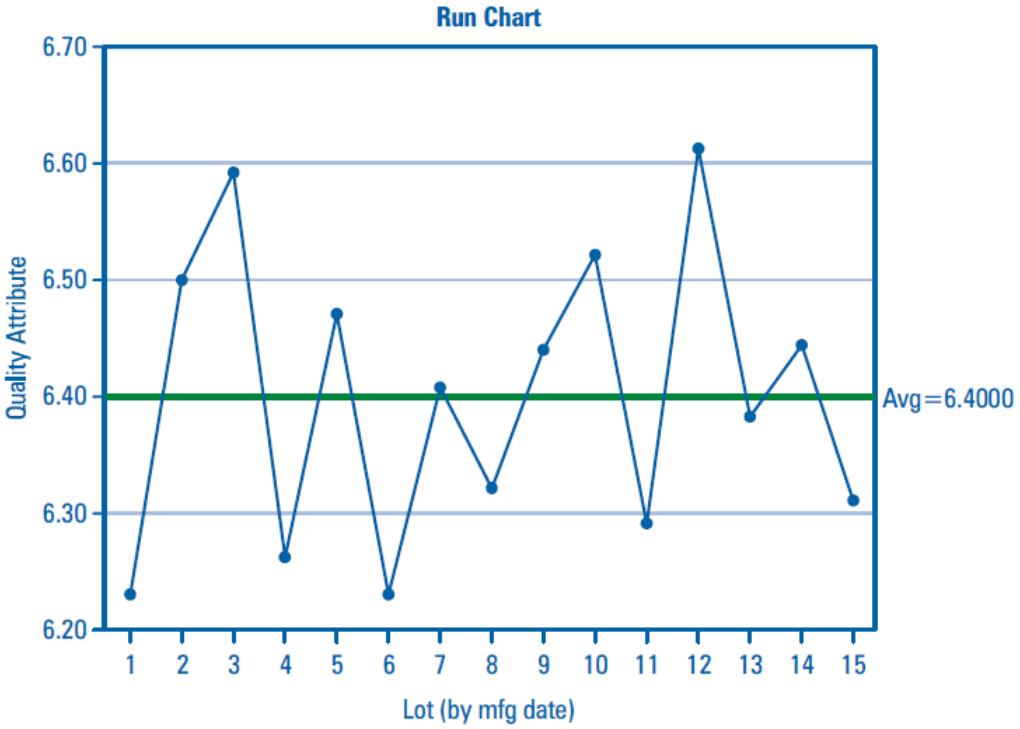
$$(\bar{X}) = 6.40$$

第五步—在收集 15 组数据点后，计算全部数据的平均值($\bar{X}$)

Step 6 — Add a line to the plot at the $\bar{X}$（原文为X ）value on the vertical axis

第六步—在纵坐标上以$\bar{X}$值绘制一条直线

Figure 5.2.2-2 Run Chart 运行图



Step 7 — Compute the Moving Range (MR) for each consecutive pair of data values by subtracting the lower value from the higher value. MR will always be a positive number.
第七步—计算每对连续数据的移动极差(MR)，通过较高的减去较低的，移动极差将总是正数。

Table 5.2.2-2 Moving Range 移动极差

Lot	Quality Attribute	Moving Range
1	6.23	
2	6.50	0.27
3	6.59	0.02
4	6.26	0.26
5	6.47	0.21
6	6.23	0.24
7	6.41	0.18
8	6.32	0.09
9	6.44	0.12
10	6.52	0.08
11	6.29	0.23
12	6.61	0.32
13	6.38	0.23
14	6.44	0.06
15	6.31	0.13

实际应为 0.09

实际应为 0.33

Step 8 — Compute the average of all $\overline{MR}$ （原文为MR) values.

= 0.184 （该数值为正确计算的移动极差平均值）

第八步—计算所有移动极差的平均值$\overline{MR}$

Step 9 — Compute the UCL using the following formula:

$$UCL = 6.40 + 2.66 \times (0.184) = 6.9$$

第九步—通过以下公式计算控制上限

Step 10 — Compute the LCL using the following formula:

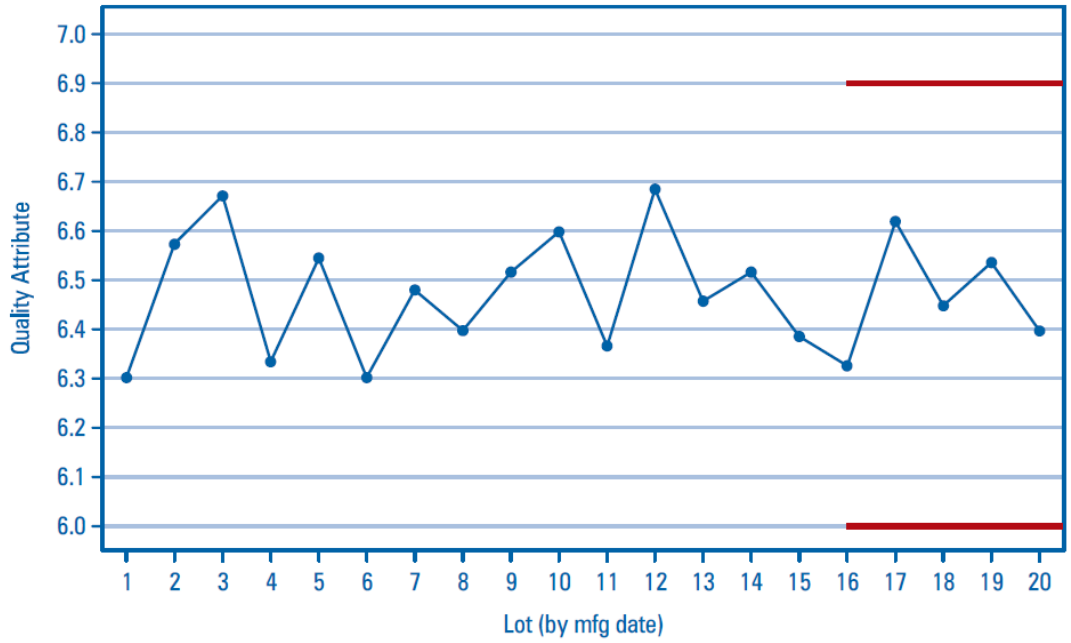
$$LCL = 6.44 - 2.66 \times (0.184) = 5.9$$

第十步—通过以下公式计算控制下限

Step 11 — Add UCL and LCL to the chart for monitoring points 16-30. These limits should not be used retrospectively on prior points. With values for Lots 16-20 added, the chart would look like:

第十一步—对监测点 16-30 添加 UCL 和 LCL 到图表。这些限度不应在前面的点应用回顾。添加 16-20 批值后，图表如图示：

Figure 5.2.2-2 Run Chart（UCL and LCL shown）运行图（UCL 和 LCL 解释）



Step 12 — After 30 points are collected, re-compute the grand average and UCL and LCL using all 30 values.
第十二步—收集 30 个点后，使用所有 30 个值重新计算总平均数和 UCL 以及 LCL。

Step 13 — Adjust the limits to the chart for monitoring data for lots 31 and higher.
第十三步—对 31 批及更多批监测数据调整限度进图表。

Step 14 — If any data falls outside a control limit, investigate the root cause. If a value is generated outside the control limits and can be assigned to a "special" cause, correct the cause. If a "special" cause is not found, evaluate the impact prior to continuing. When a special cause can be determined, the data point should continue to be included on the chart but should be excluded from calculations of the average, UCL and LCL.
第十四步—如果任何数据超出控制限度，调查其根本原因。如果找不到一个“特殊”原因，继续进行前评估影响。当一个特殊原因可以确定时，数据点应继续包括到图表中且应排除在平均计算值外，UCL 和 LCL。

5.3 Moving Range Control Charts 移动极差控制图

5.3.1 Technical Details 技术细节

Step 1 — Place data or statistics in time-order
步骤 1—在时序中输入数据或统计数据

Step 2 — As soon as the second data value is collected, compute MR for each consecutive pair7 by subtracting the lower value from the higher value. MR will always be a positive number.
步骤 2—一旦收集到第二个数据值，就通过从高值减去低值计算每个连续对的 MR，MR 恒为正数。
Step 3 — Create a plot of the MR data with the range of data values on the vertical axis and the timing of the data on the horizontal axis. The plot should be created as soon as the first MR value is available.
步骤 3-用数据值范围在纵轴以及数据时间在横轴创建一个 MR 数据图点。一旦第一个 MR 值可用，就应创建该图点。

Step 4 — Connect plotted points with lines.
步骤 4-以线连接图点。

Step 5 — Add subsequent MR data values and connect to the previously plotted point as the data become available.
步骤 5-当数据可用，添加随后的 MR 数据值并连接前面的图点。

Step 6 — After 16 data points are collected, compute the overall average of the MR values. This is abbreviated as $\overline{MR}$.

步骤 6-收集 16 个数据点后，计算 MR 值的总体平均值。总体平均值缩写为$\overline{MR}$。

Step 7 — Add a line to the plot at the $\overline{MR}$ value on the vertical axis.

步骤 7-在纵轴$\overline{MR}$值处添加线到图点

Step 8 — Compute UCL using the following formula:

$$\text{UCL} = 3.268 \times \overline{MR}$$

用下面的公式计算 UCL：

Step 9 — Set L C L = 0.
步骤 9-设定 LCL=0

Step 10 — Add UCL and LCL to the chart for monitoring points 16-30. These limits should not be used retrospectively on prior points.
步骤 10-将 UCL 和 LCL 添加到监测点 16-30 的图表上。这些限度不应回顾性地应用在前面的点。

Step 11 — Adjust UCL to the chart for monitoring points 31 +
步骤 11-对监测点 31 以后的监测点的图表调整 UCL

Step 12 — If any data fall outside a control limit, investigate the root cause. If a value is generated outside the control limits and can be assigned to a "special" cause, correct the cause. If a "special" cause is not found, evaluate the impact prior to continuing. When a special cause can be determined, the data point

should continue to be included on the chart, but it should be excluded from future calculations of the average and UCL.
步骤 12-如果任何数据落在控制限外，调查根源。如果一个值落在控制限外且能到一个“特殊”原因，那么就纠正该原因。如果找不到一个特殊原因，那么就在继续之前评估其影响。当可以确定特殊原因时，数据点应继续包括到图表中但应排除在未来的平均值和 UCL 计算之外。

5.3.2 Example 实例

Using the example data from Section 3.1.2.1, the first 15 data points represent the first 15 lots in timeorder:
使用 3.1.2.1 部分的举例数据，前 15 数据点代表时序中前 15 批

Step 1 — Place data or statistics in time-order.
步骤 1-在时序中输入数据或统计数据

Table 5.3.2-1 Lot Data in Time Order 按时间顺序统计的批数据

Lot	Quality Attribute
1	6.23
2	6.50
3	6.59
4	6.26
5	6.47
6	6.23
7	6.41
8	6.32

Lot	Quality Attribute
9	6.44
10	6.52
11	6.29
12	6.61
13	6.38
14	6.44
15	6.31

Step 2 — As soon as the second data value is collected, compute MR for each consecutive pair[8] of data values by subtracting the lower value from the higher value. MR will always be a positive number.
一旦收集到第二个数据值，就通过从高值减去低值计算每个连续对的 MR，MR 恒为正数。

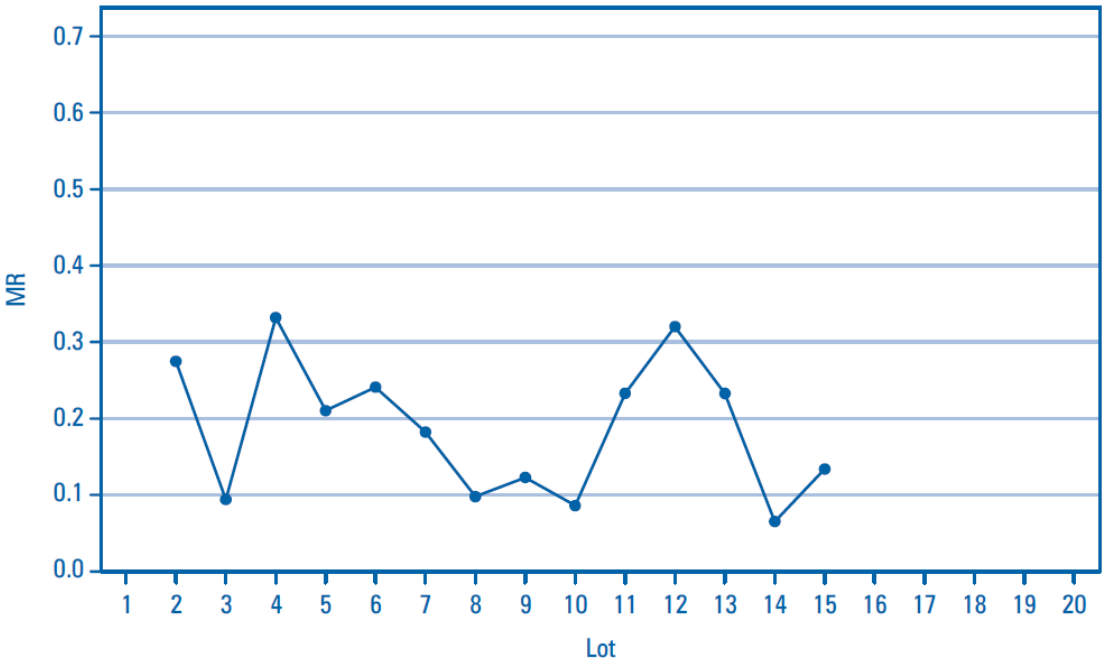
Table 5.3.2-2 Lot Data with Moving Range 有移动极差的批数据

Lot	Quality Attribute	Moving Range
1	6.23	
2	6.50	0.27
3	6.59	0.09
4	6.26	0.33
5	6.47	0.21
6	6.23	0.24
7	6.41	0.18
8	6.32	0.09
9	6.44	0.12
10	6.52	0.08
11	6.29	0.23
12	6.61	0.32
13	6.38	0.23
14	6.44	0.06
15	6.31	0.13

Step 3 —Create a plot of the MR data with the range of data values on the vertical axis and the time sequence of the data on the horizontal axis. The plot should be created as soon as the first MR value is available.
步骤 3-用数据值范围在纵轴以及数据时间在横轴创建一个 MR 数据图点。一旦第一个 MR 值可用，就应创建该图点。

Step 4 — Connect plotted points with lines:
步骤 4-以线连接图点。

Figure 5.3.2-1 MR Chart 移动极差（MR）图



Step 5 — Add subsequent MR data values and connect to the previously plotted point as the data become available.
步骤 5-当数据可用，添加随后的 MR 数据值并连接前面的图点。

Step 6 — After 15 data points are collected, compute the overall average of the MR values. This is abbreviated as $\overline{MR}$ (MR-bar):

$\overline{MR}$ = 0.184

步骤 6-收集 16 个数据点后，计算 MR 值的总体平均值。总体平均值缩写为 MR。

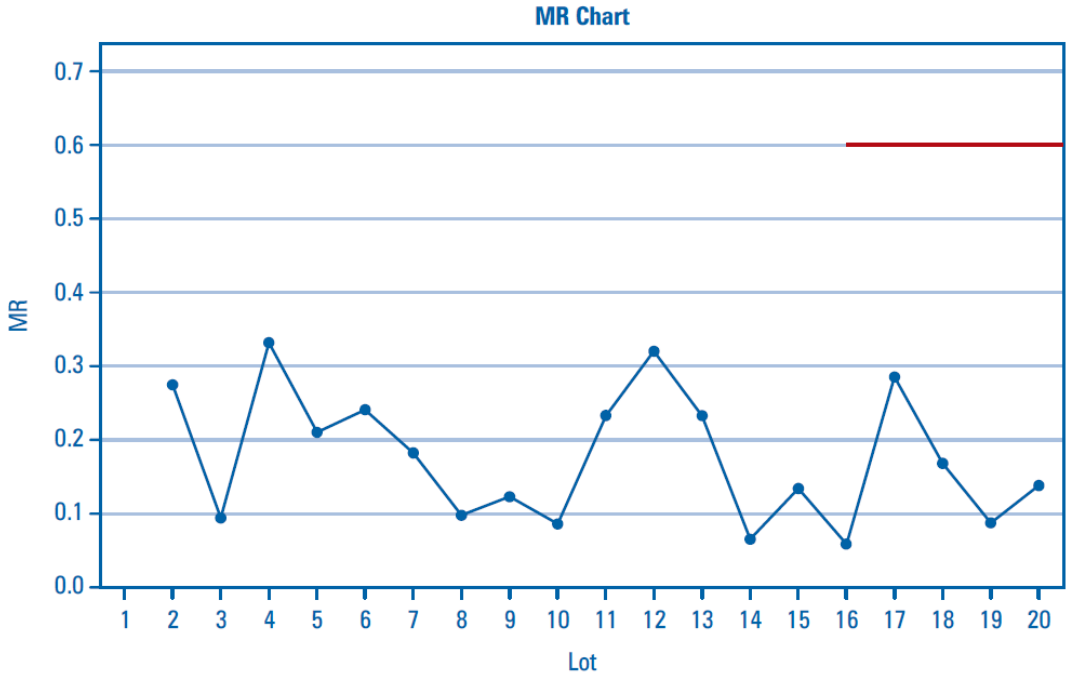
Step 7 — Add a line to the plot at the MR value on the vertical axis.
步骤 7-在纵轴 MR 值处添加线到图点。

Step 8 — Compute UCL using the following formula:
UCL = 3.268 x 0.184 = 0.601
步骤 8-用下面的公式计算 UCL：

Step 9 — Set L C L = 0
步骤 9-设定 LCL=0

Step 10 — Add MR, UCL and LCL to the chart for monitoring points 16-30. These limits should not be used retrospectively on prior points:
步骤 10-将 MR、UCL 和 LCL 添加到监测点 16-30 的图表上。这些限度不应回顾性地应用在前面的点。

Figure 5.3.2-2 Moving Range Chart (Upper & Lower Limits shown) 移动极差图（显示上限和下限）



Step 11 — After 30 data points are collected, re-compute UCL
步骤 11-收集到 30 个数据点后，重新计算 UCL.

Step 12 — Adjust UCL to the chart for monitoring points 31 and higher.
步骤 12- 调整监测点 31 以后的监测点的图表的 UCL

Step 13 — If any data fall outside a control limit, investigate the root cause. If a value is generated outside the control limits and can be assigned to a "special" cause, correct the cause. If a "special" cause is not found, evaluate the impact prior to continuing. When a special cause can be determined, the data point should continue to be included on the chart, but it should be excluded from calculations of the average, UCL.
步骤 13-如果任何数据落在控制限外，调查根源。如果一个值落在控制限外且能到一个“特殊”原因，那么就纠正该原因。如果找不到一个特殊原因，那么就在继续之前评估其影响。当可以确定特殊原因时，数据点应继续包括到图表中但应排除在未来的平均值和 UCL 计算之外。

5.4 Average and Variability Charts 均值图和变异性图

5.4.1 Technical Details 技术要点

Step 1 - Identify the size of each sample set， commonly referred to as a subgroup. Subgroups should be rational， that is， should represent a range of results that are intended to be very similar. That will allow unintended changes between subgroups to be more easily distinguished.
步骤 1-确定每一样本量大小，通常指一个子群。子群的建立应合理，能够代表类似结果的范围。这便于区分各子群间非预期的变动。

Step 2 - Collect the specified number of samples for each subgroup at reasonable intervals during the process or lot.
步骤 2-以适当间隔收集过程或批内每一子群指定数量的样本。

Step 3 - Begin collecting and recording data along with date/time information.
步骤 3-按照日期/时间收集并记录数据。

Step 4 – Compute the average for the first subgroup
步骤 4-计算第一子群的平均值。

Step 5 – Plot the subgroup average on the $\bar{X}$ Chart.
步骤 5-将子群的平均值画在控制图上

Step 6 – Compute the measure of variability for each subgroup by either:
步骤 6-通过以下一种方式计算每一子群变异

1. computing the range for each subgroup by subtracting the smallest value from the largest value within the subgroup. Or
   用子群内最大值减去最小值，得到极差。或

2. computing the average standard deviation in two parts. First， for each rational subgroup， calculate the standard deviation by taking the square root of the sum of the square of the individual values minus the average value， which is then divided by the number of samples within the subgroup minus one. Next， sum the standard deviation of each of the historical subgroups and divide by the number of historical subgroups.
分两步计算平均值标准偏差。首先，计算每一子群标准偏差，取每一数值减去平均值后求得平方根，相加后再取平方根。然后将每一子群的标准偏差相加，再除以子群数。

Step 7 –Plot the measure of variability for the first subgroup on the variability chart.
步骤 7-将第一子群变异值画在控制图上。

Step 8 - Continue collecting samples and compute the average and range (or standard deviation) for each sample set. Then， plot the averages and ranges on the appropriate chart and connect the points with lines.
步骤 8-继续收集每一样本，计算平均值和极差（或标准偏差）。再将平均值和极差画在控制图上，用线将各点连接起来。

Step 9 - After 15 subgroups of data are collected:
步骤 9-在收集到 15 个子群的数据后

1. compute the grand average of all the subgroup averages
计算所有子群平均值的总体平均。
2. compute the average of all subgroup ranges
计算所有子群极差的平均值

Step 10 - Plot the grand average on the X Chart
步骤 10-将总体平均值画在均值控制图上

Step 11- Plot the average range on the Range Chart.
步骤 11-将平均极差画在控制图上。

Step 12 - Compute UCL for the Variability Chart using the following formula:
步骤 12-用下式计算控制图的 UCL。

Range 极差

$UCL = D_4 \bar{R}$

Sample Size	2	3	4	5
D_4	3.267	2.575	2.282	2.115

Standard Deviation 标准偏差

$UCL = B_4 \bar{S}$

Sample Size	6	7	8	9
B_4	1.970	1.882	1.815	1.761

Step 13 – Compute LCL for the Variability Chart using the following formula:
步骤 13-用下式计算控制图的 LCL：

Range 极差

LCL =$D_3\bar{R}$

Sample Size	2	3	4	5
D_3	0	0	0	0

Standard Deviation 标准偏差

LCL =$B_3\bar{S}$

Sample Size	2	3	4	5
B_3	0.030	0.118	0.185	0.239

Step 14 - Plot UCL and the LCL on the Variability Chart for monitoring variability beyond sub-group 15.
步骤 14 –将 UCL 和 LCL 画在控制图上，控制 15 子群之外的变动。

Step 15 - Compute UCL for the Average Chart using the following formula:
步骤 15 –用下式计算 UCL
Range 极差

UCL =X+$A_2\bar{R}$

Sample Size	2	3	4	5
A_2	1.880	1.023	0.729	0.577

Standard Deviation 标准偏差

UCL =X+$A_3\bar{S}$

Sample Size	6	7	8	9
A_3	1.287	1.182	1.099	1.032

Step 16 - Compute LCL for the Average Chart using the following formula:
步骤 16 –用下式计算 LCL：

Range 极差

LCL =X-$A_2\bar{R}$

Sample Size	2	3	4	5
A_2	1.880	1.023	0.729	0.577

Standard Deviation 标准偏差

LCL =X-$A_3\bar{S}$

Sample Size	6	7	8	9
A_3	1.287	1.182	1.099	1.032

Step 17 - Plot UCL and the LCL on the Average Chart for monitoring subgroups 15 and beyond.
步骤 17 –将 UCL 和 LCL 画在控制图上，控制 15 子群之外的变动。

Step 18- Continue collecting data for subgroups 16 and beyond. Update the Range (or s) and X Charts with each subgroup's variability and average.
步骤 18 –继续收集 16 及之后子群的数据。根据每一子群的变动值和平均值，更新极差（或标准偏差）和控制图。

Step 19 - If any subgroup's variability or average falls outside the control limits， investigate the root cause. If a "special" cause can be assigned， correct the cause. If a "special" cause is not found， evaluate the impact prior to continuing. When a special cause can be assigned， the data point should continue to be included on the chart; it should be excluded from calculations of ranges， averages and control limits
步骤 19 –如果任何子群的变动或平均值落在控制限之外，应调查根本原因。如果可以找到“特殊”原因，则进行纠正。如果没有发现“特殊”原因，应在继续操作前对影响进行评估。如果可以明确“特殊”原因，则该数据点仍可保留在控制图上，但不参与极差、平均值和控制限的计算。

Step 20 - After 30 subgroups are collected， re-compute the control limits
步骤 20 –在收集 30 个子群数据后，重新计算控制限。

Step 21 - Adjust the control limits to the chart for monitoring subgroups 31 and beyond.
步骤 21 –调整控制限，对 31 及以后的子群进行控制。

5.4.2 Example 举例

Step 1 - Identify the size of each sample set， commonly referred to as a subgroup. Subgroups should be rational， that is， should represent a range of results that are intended to be very similar. That will allow unintended changes between subgroups to be more easily distinguished.
步骤 1 –确定每一样本量大小，通常指一个子群。子群的建立应合理，能够代表类似结果的范围。这便于区分各子群间非预期的变动。

A tub of 30 vials is filled using a filling machine with six filling nozzles. Since the vials are filled at approximately the same time under the same conditions， it is reasonable to expect the weight of the vials from each nozzle to be similar. Therefore, five vials will be sampled from the tub for nozzle #1 fills.
用 6 针灌装机填充 30 个瓶子。因为瓶子在同等环境下在大约同一时间灌装，可以认为每一针头灌装的瓶子的重量是类似的。因此，可取 1 号针头灌装的 5 个瓶子。

For the purposes of illustration， this example will describe the establishment of control limits from the initial data generated within a run. In practice， it may be more common to have pre-established expectations for process performance in place as a run commences.
本例将描述如何根据初始数据建立控制限。实际上，通常在开始操作时，已经初步确定了工艺性能的预期。

Step 2 - Collect the specified number of samples for each subgroup at reasonable intervals during the process or lot.
步骤 2 –以适当间隔收集过程或批内每一子群指定数量的样本。

Due to the time required to weigh the vials, the sample of five for nozzle #1 will be weighed every 15 minutes.
因为需要时间称量瓶子重量，每 15 分钟称量一次 1 号针头灌装的样品。

Step 3 - Begin collecting and recording data along with date/time information.
步骤 3 –按照日期/时间收集并记录数据。

The following data were collected for the first time point:
在第一时间点收集一下数据

Table 5.4.2-1 Sample Data Collection Table
表 5.4.2-1 样品数据收集表

Date/time	3/16 1:00	3/16 1:15	3/16 1:30	3/16 1:45	3/16 2:00	3/16 2:15	3/16 2:30	3/16 2:45	3/16 3:00	3/16 3:15	3/16 3:30	3/16 3:45	3/16 4:00	3/16 4:15	3/16 4:30
Sample 1	6.46														
Sample 2	6.59														
Sample 3	6.54														
Sample 4	6.31														
Sample 5	6.35														

Step 4 – Compute the average for the first subgroup.
步骤 4 –计算第一子群的平均值。

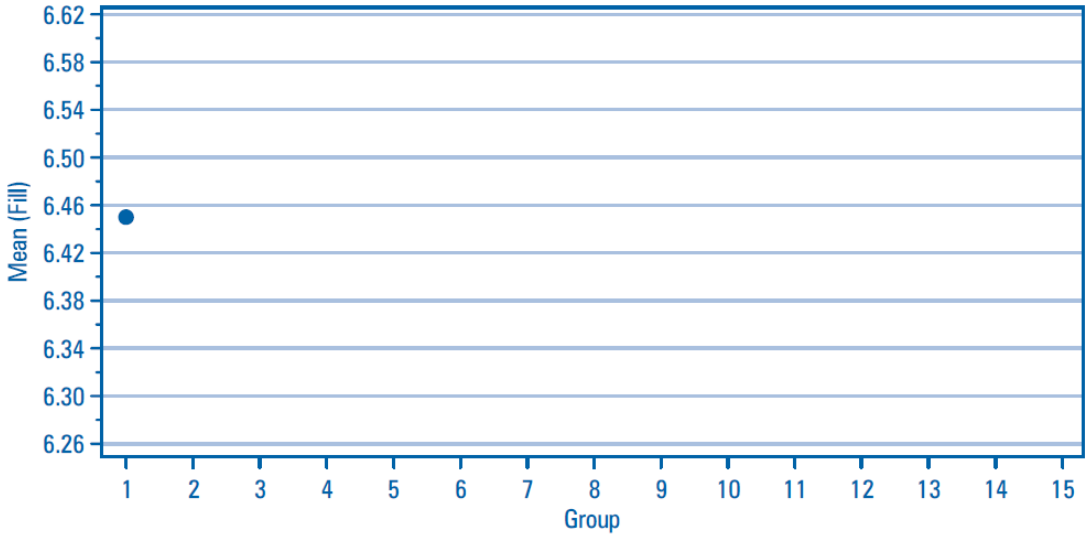
Table 5.4.2-2 Sample Average 0ata Collection Table 样本平均值数据表

Date/time	3/16 1:00	3/16 1:15	3/16 1:30	3/16 1:45	3/16 2:00	3/16 2:15	3/16 2:30	3/16 2:45	3/16 3:00	3/16 3:15	3/16 3:30	3/16 3:45	3/16 4:00	3/16 4:15	3/16 4:30
Sample 1	6.46														
Sample 2	6.59														
Sample 3	6.54														
Sample 4	6.31														
Sample 5	6.35														
Average	6.45														

Step 5 – Plot the subgroup average on the $\bar{X}$ Chart.

步骤 5 –将子群的平均值画在平均值控制图上

Figure 5.4.2-1 Sample $\bar{X}$ Chart 控制图



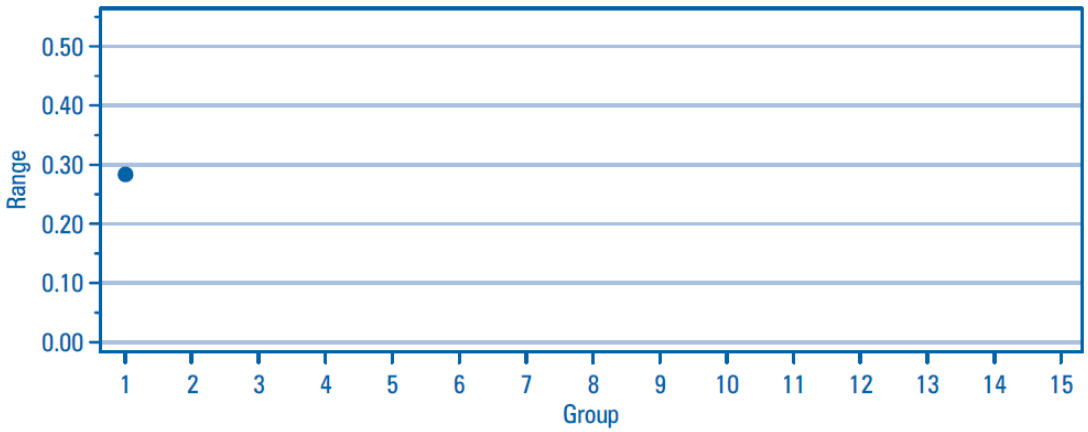
Step 6 - Compute the range for each subgroup by subtracting the smallest value from the largest value within the subgroup.
步骤 6 –用每一组内最大值减去最小值，计算每一子群的极差。

Table 5.4.2-3 Sample 0ata Range Collection Table 样本极差收集表

Date/time	3/16 1:00	3/16 1:15	3/16 1:30	3/16 1:45	3/16 2:00	3/16 2:15	3/16 2:30	3/16 2:45	3/16 3:00	3/16 3:15	3/16 3:30	3/16 3:45	3/16 4:00	3/16 4:15	3/16 4:30
Sample 1	6.46														
Sample 2	6.59														
Sample 3	6.54														
Sample 4	6.31														
Sample 5	6.35														
Average	6.45														
Range	0.28														

Step 7- plot the range for the first subgroup on the range chart
步骤 7 –将第一子群的极差画在极差控制图上

Figure 5.4.2-2 Sample Range Chart 样本极差图



Step 8 - Continue collecting samples and compute the average and range for each sample set group. Then，plot the group averages on the appropriate chart and connect the points with lines.
步骤 8 –继续收集每一样本，计算平均值和极差（或标准偏差）。再将平均值和极差画在控制图上，用线将各点连接起来。

Table 5.4.2-4 Sample Data Average and Range Collection Table 样本平均值和极差收集表

Date/time	3/16 1:00	3/16 1:15	3/16 1:30	3/16 1:45	3/16 2:00	3/16 2:15	3/16 2:30	3/16 2:45	3/16 3:00	3/16 3:15	3/16 3:30	3/16 3:45	3/16 4:00	3/16 4:15	3/16 4:30
Sample 1	6.46	6.47	6.47	6.47	6.39	6.42	6.24	6.47	6.35	6.37	6.40	6.56	6.48	6.66	6.55
Sample 2	6.59	6.36	6.57	6.38	6.46	6.38	6.37	6.45	6.37	6.37	6.50	6.36	6.26	6.28	6.13
Sample 3	6.54	6.30	6.54	6.39	6.53	6.36	6.38	6.42	6.39	6.56	6.65	6.36	6.50	6.42	6.51
Sample 4	6.31	6.40	6.46	6.30	6.45	6.47	6.52	6.51	6.32	6.41	6.47	6.43	6.42	6.50	6.49
Sample 5	6.35	6.48	6.45	6.37	6.48	6.47	6.52	6.27	6.48	6.60	6.42	6.37	6.74	6.56	6.32
Average	6.45	6.40	6.50	6.38	6.46	6.42	6.40	6.42	6.38	6.46	6.49	6.42	6.48	6.48	6.40
Range	0.28	0.19	0.12	0.17	0.15	0.11	0.28	0.24	0.16	0.23	0.24	0.20	0.48	0.38	0.42

Figure 5.4.2-3 Sample Average $\bar{X}$ Chart 样本平均值控制图

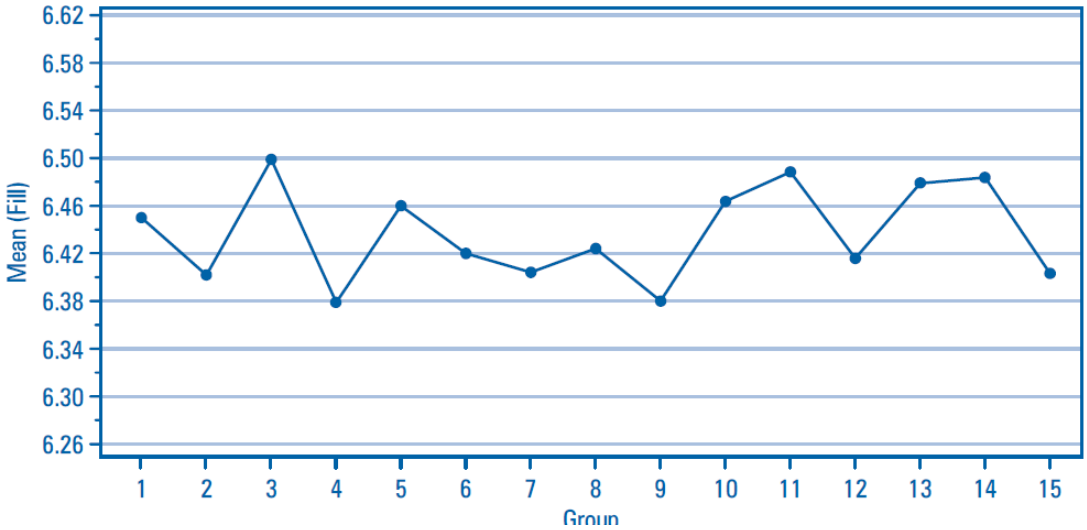
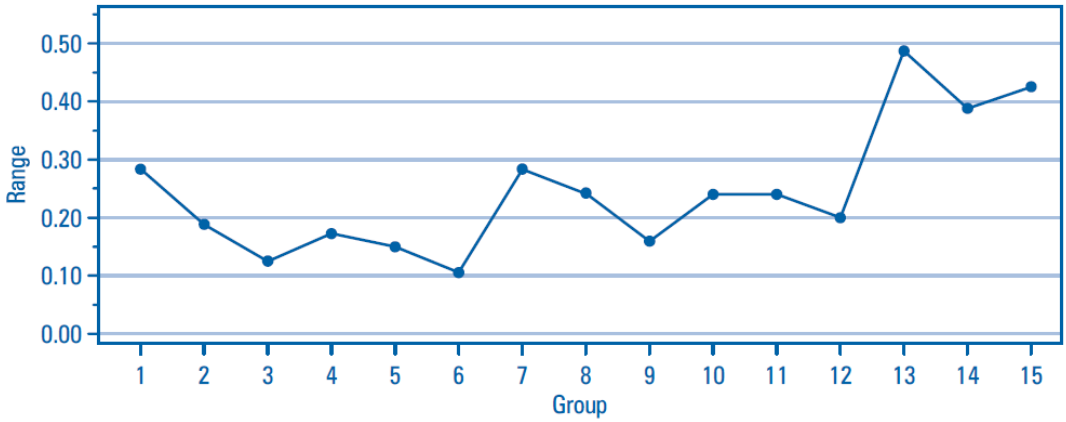


Figure 5.4.2-4 Sample Range $\bar{X}$ Chart 样本极差控制图



Step 9 - After 15 subgroups of data are collected compute the grand average of all the subgroup averages.
步骤 9 –在收集 15 个子群的数据后，计算所有子群均值的总体平均值

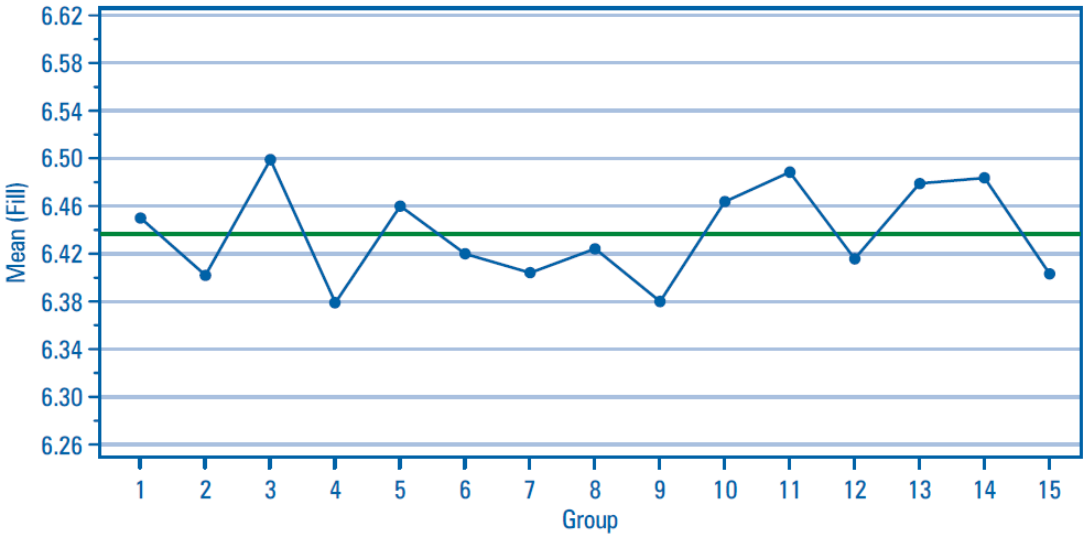
$$\bar{X} = \frac{6.45+6.40+6.50+6.38+6.46+6.42+6.40+6.24+6.38+6.46+6.49+6.42+6.48+6.48+6.40}{15} = 6.436$$

Compute the average of all subgroup ranges in a similar fashion
用类似方法计算各子群极差的平均值

$$\bar{R} = 0.243$$

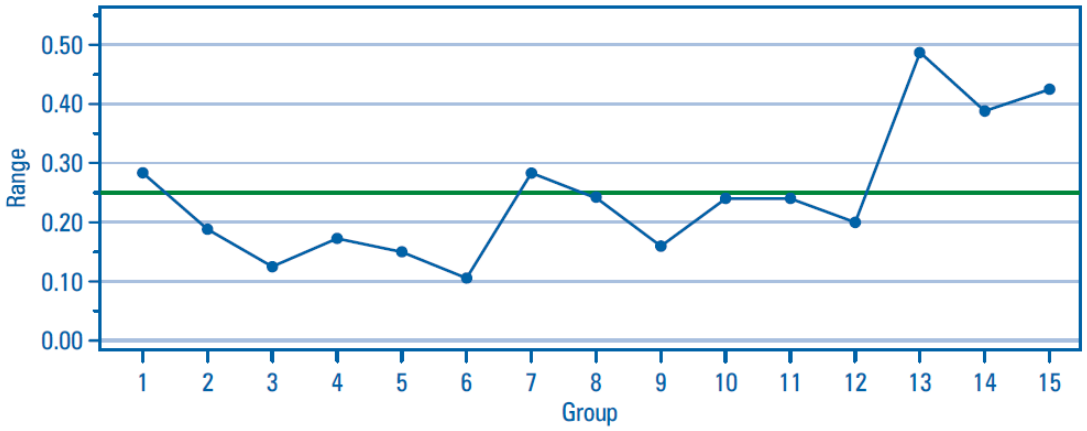
Step 10 - Plot the grand average on the x Chart
步骤 10 –将总体平均值画在均值控制图上

Figure 5.4.2-5 Sample Grand Range $\bar{\bar{X}}$ Chart 均值控制图-总体均值



Step 11 – Plot the average range on the Range Chart
步骤 11 –将平均极差画在控制图上。

Figure 5.4.2-6 Sample X Chart of Average Range on the Range 极差控制图-平均极差



Step 12 - Compute UCL for the Range Chart using the following formula:
步骤 12 –用下式计算极差控制图的 UCL。

$$UCL=D_4\bar{R}$$

$$UCL=2115\times 0.243=0.515$$

Sample Size	2	3	4	5
D_4	3.267	2.575	2.282	2.115

Step 13 - Compute LCL for the Range Chart using the following formula:
步骤 13 –用下式计算极差控制图的 LCL：

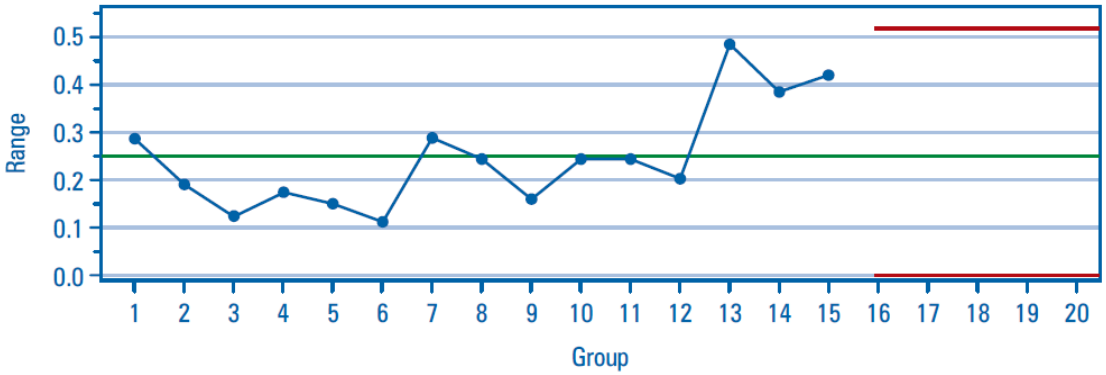
$$LCL=D_3\overline{R}$$

$$LCL=0\times 0.243=0$$

Sample Size	2	3	4	5
D_3	0	0	0	0

Step 14 – Plot the UCL and the LCL on the Range Chart for monitoring Ranges beyond subgroup 15.
步骤 14 –将 UCL 和 LCL 画在极差控制图上，控制 15 子群之后的极差。

Figure 5.4.2-7 Sample UCL and the LCL on the Range Chart 极差图-样本 UCL 和 LCL



Step 15 - Compute UCL for the Average Chart using the following formula:
步骤 15 –用下式计算均值控制图的 UCL

$$UCL=X+A_2\overline{R}$$

$$UCL=6.436\times(0.577\times 0.243)=6.57$$

Sample Size	2	3	4	5
A_2	1.880	1.023	0.729	0.577

Step 16 - Compute LCL for the Average Chart using the following formula:
步骤 16 –用下式计算均值控制图的 LCL：

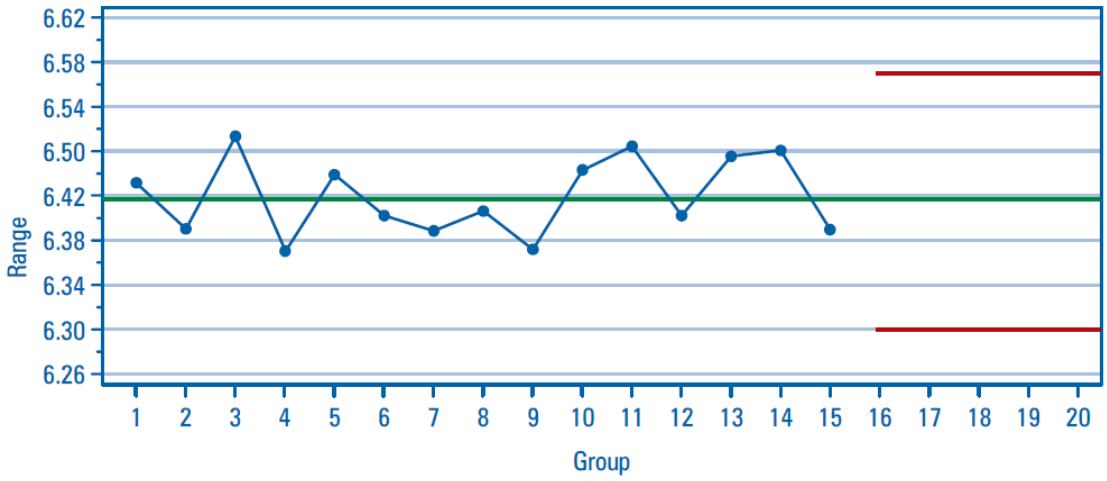
$$UCL=X-A_2\overline{R}$$

$$UCL=6.436-(0.577\times 0.243)=6.30$$

Sample Size	2	3	4	5
A_2	1.880	1.023	0.729	0.577

Step 17 - Plot the UCL and the LCL on the Average Chart for monitoring subgroups 15 and beyond.
步骤 17 –将 UCL 和 LCL 画在均值控制图上，控制 15 子群之后数据的变动。

Figure 5.4.2-8 Sample UCL and the LCL on the Average Chart 均值控制图-样本 UCL 和 LCL



Step 18 - Continue collecting data for subgroups 16 and beyond. Update the Range and X Charts with each subgroup's range and average.
步骤 18 –继续收集 16 及之后子群的数据。根据每一子群的极差和平均值，更新极差和均值控制图。

Table 5.4.2-5 Sample Average and Range Data Table 样本均值和极差数据表

Date/time	3/16 4:45	3/16 5:00	3/16 5:15	3/16 5:30	3/16 5:45	3/16 6:00	3/16 6:15	3/16 6:30	3/16 6:45	3/16 7:00	3/16 7:15	3/16 7:30	3/16 7:45	3/16 8:00	3/16 8:15
Sample 1	6.55	6.45	6.43	6.32	6.56										
Sample 2	6.43	6.49	6.33	6.47	6.42										
Sample 3	6.34	6.61	6.38	6.41	6.33										
Sample 4	6.58	6.48	6.46	6.41	6.47										
Sample 5	6.49	6.50	6.43	6.26	6.42										
Average	6.48	6.51	6.41	6.37	6.44										
Range	0.25	0.16	0.13	0.21	0.23										

Figure 5.4.2-9 Sample Average and Range $\bar{X}$ Chart 样本极差控制图

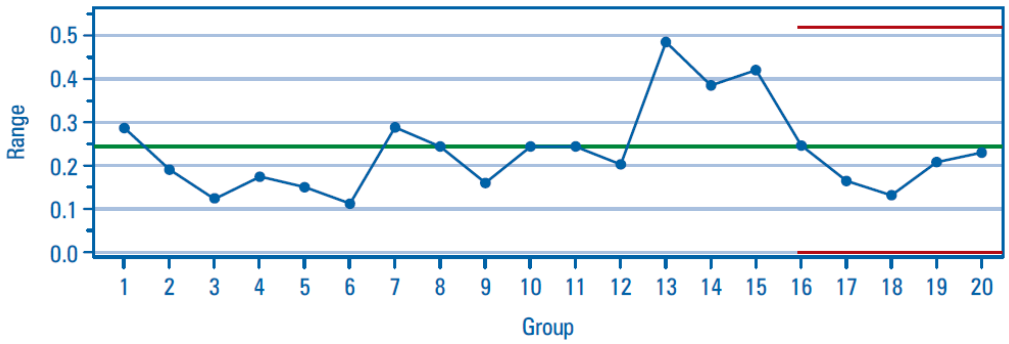
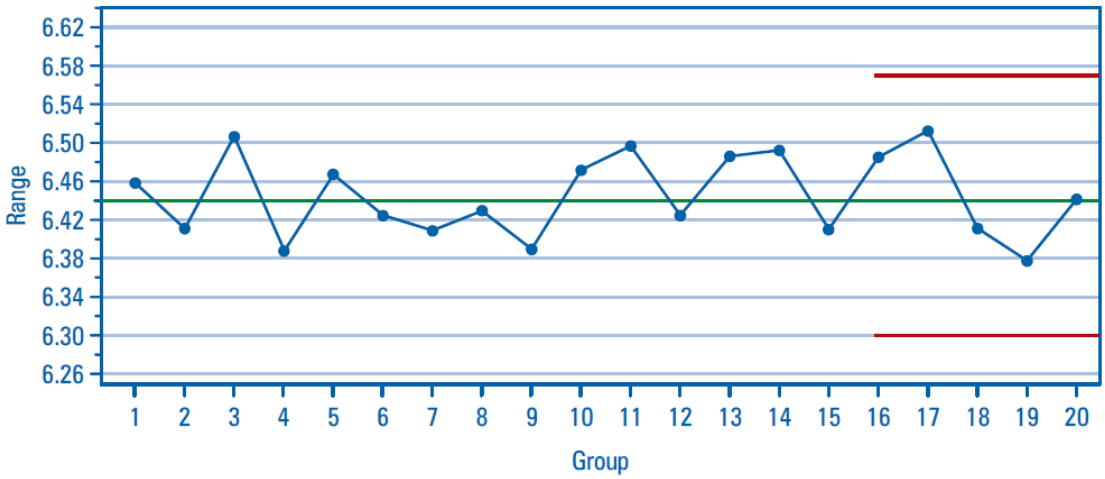


Figure 5.4.2-10 Sample Average and Range $\bar{X}$ Chart (UCL & LCL) 样本均值控制图



Step 19 - If any subgroup range or average falls outside the control limits， investigate the root cause. If a "special" cause can be assigned， correct the cause. If a special cause is not found， evaluate the impact prior to continuing. When a special cause can be assigned， the data point should continue to be included on the chart， but it should be excluded from calculations of ranges， averages and control limits.
步骤 19 –如果任何子群的变动或平均值落在控制限之外，应调查根本原因。如果可以找到“特殊”原因，则进行纠正。如果没有发现“特殊”原因，应在继续操作前对影响进行评估。如果可以明确“特殊”原因，则该数据点仍可保留在控制图上，但不参与极差、平均值和控制限的计算。

Step 20 - After 30 subgroups are collected， re-compute the control limits
步骤 20 –在收集 30 个子群数据后，重新计算控制限。

Step 21 - Adjust the control limits to the chart for monitoring subgroups 31 and beyond.
步骤 21 –调整控制限，对 31 及以后的子群进行控制。

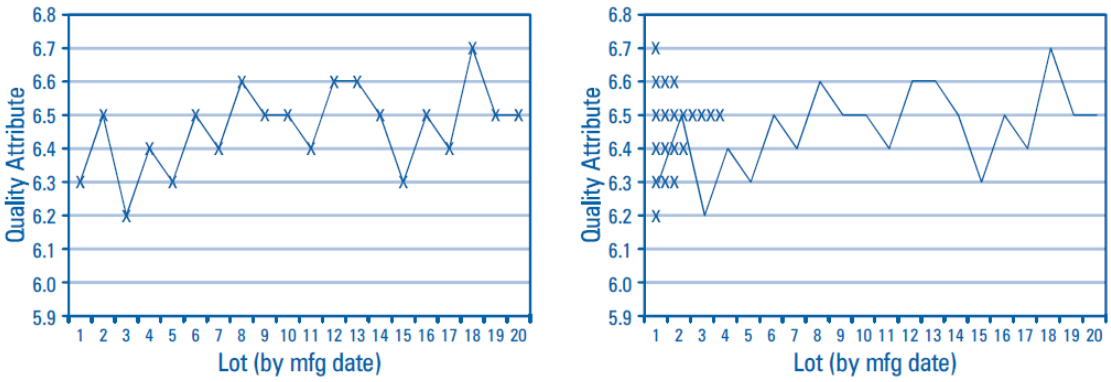
5.5 Histograms 直方图

5.5.1 Example Case Worked in Parallel with Theory/Principles 示例案例与理论/工作原理

Understanding how past data are distributed provides useful information about how they might be Distributed in the future, assuming that the future will continue to look like the past. If the points in the example Run Chart were replaced with X's, the figure would look like:
了解过去的数据分布提供的有用的关于数据未来分布的信息,假设未来将继续像过去的分布。如果分示例点的运行图表被替换为 X 的,这个数字将会看起来像:

Figure 5.5.1-1 Sample Average and Range $\bar{X}$ Chart (UCL & LCL)

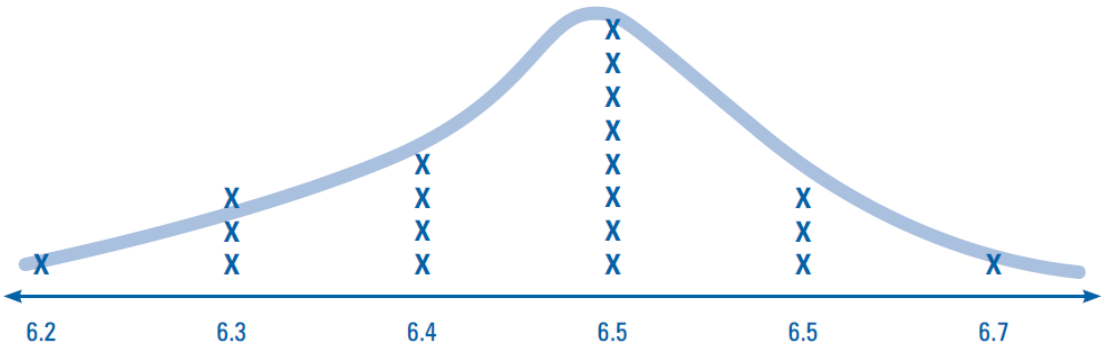
样品均值和极差控制图（控制上限和控制下限）



After collecting the X's for each Quality Attribute Value, the X's would provide a first look at the distribution of results:
收集 X 的每一个质量属性值后，X 的将提供一个直观的分布结果：

When examined separately, the distribution of X's seems to have somewhat of a symmetrical "bell" shape.
当分别检查时，X 的分布规律看起来像对称的"钟"性。

Figure 5.5.1-2 Sample Statistical Distribution of Results 样品统计分布结果



A statistical distribution assumed for many calculations that has a bell-shape is the Normal Distribution. For the data in this example, the average is 6.5 and the standard deviation is 0.1. The standard deviation is a measure of the variability of the data.
经过多次计算的统计分布假定像“钟”形的称为正态分布。对于这个示例中的数据,平均值为 6.5,标准偏差为 0.1。标准的偏差是一个数据变异性的测量。

5.6 $C_{pk'}$，P_{pk} for process Capability 过程能力 Cpk,Ppk 值

5.6.1 General Procedure for Finding C_{pk} and P_{pk} Cpk和Ppk的一般求得方法

Step 1- collect a truly representative sample from the process using good sampling techniques. The sampling plan can be random or systematic. The sample should be as large as possible but need not be more than 100 initially.
步骤 1－利用优良的取样技术从工艺收集真实的、典型的样本。样本抽样计划可以是随机的或系统的。样本（量）应该尽可能的大但需要不超出最初 100（组）

Step 2- calculate the average and the variability estimate.
步骤 2－计算平均值和可变性估计

Step 3- calculate C_{pk} (and /or P_{pk}) .
步骤 3－计算 Cpk (和 /或 Ppk)

C_{pk} = Min (Cpl,CPu)
C_{pk} =最小(Cpl,CPu)

C_{pl}= (Average-Lower Specification Limit)/3*Variability Estimate
C_{pl}=（平均值-标准下限）/3*可变性估计

C_{pu}= (Upper Specification Limit-Average)/3*Variability Estimate
C_{pu}=(标准上限-平均值) /3*可变性估计

Step 4-Interpret the results in terms of the process
步骤 4－解释该过程的结果

P_{pk} is similarly calculated, except that instead of using the estimate of process variability, it uses the actual variability observed within the sample set.

Ppk 是近似的计算，除用工艺变异性代替之外，它使用实际的在样品集中的变异性。

If the process is capable of reliably achieving specifications, the index will be greater than 1.o. Most applications attempt to achieve at least 1.33. Well-controlled and capable processes sometimes achieve a desired value of 2.0.
如果该过程稳定可靠的达到标准，这指数将大于 1.0。大多数过程要求该值达到 1.33。对控制很好并且非常稳定可靠的过程该值能达到 2.0。

5.6.2 Example Cpk for a Single Group 单组样品的Cpk举例

Step 1-Collect the data, which in this case is a single group of 30 values all taken at the same time.
步骤 1－收集数据，在这种下同时收集单组 30 个数据。

Table 5.6.2-1 Example of Cpk for a Single Group 单组样品的 Cpk 举例

90.8	94.6	101.2	98.2	101.4	98.3
99.0	93.8	105.7	102.3	93.4	104.5
98.5	101.6	106.9	105.6	98.0	98.7
105.3	96.2	96.2	100.6	102.7	103.7
97.9	96.8	98.6	101.5	98.8	100.1

Step 2-Calculate the average and Variability estimate
步骤 2 -计算平均值和变异性估计

The grand average of the thirty values is 99.6914
这 30 个数据的平均值为 99.6914
The standard deviation of all the data taken as one group is 4.1174
这组数据的标准偏差是 4.1174

Step 3- The example specification criteria are 90%-100%.
步骤 3－案例规格标准在 90%-100%（我觉得是印刷错误，应为 110%）

C_{pl}= (99.6914-90.0)/（3*4.1147）=0.78
C_{pu}= (110.0-99.6914)/ （3*4.1147）=0.83
C_{pk}=Min（0.78,0.83）=0.78

Step 4-Cpk needs to be greater than 1.0 for the natural variability of the data to lie within the specification range. In this example, the process is apparently not capable of meeting the specification limits. Even if the calculated C_{pk} is greater than 1.0, it is possible than the true, but unknown, value is actually less than 1.0 since C_{pk} is a random variable. If many samples are taken, the result would be a distribution of C_{pk} values. To address the variability issue, find the lower 95% confidence interval for C_{pk} as in Table 5.6.6-2.
步骤 4－在标准范围内随机变化的一组数据的 C_{pk} 值需大于 1.0。在这个例子中，过程能力显然不能满足标准的要求。即使计算的 C_{pk} 大于 1.0，这也可能是真实的，但不确定，由于偶然因素 C_{pk} 实际计算值小于 1.0。如果是多个样本，那么就会形成一个 C_{pk} 值的分布。为了更好地了解化的规律，找出低于 95%置信区间 C_{pk} 见表 5.6.2-2.

Table 5.6.2-2 Example of 95% confidence interval for C_{pk} 案例 Cpk 的 95%置信区间

Size Est. C_{pk}	5	10	15	20	25	30	40	50	75	100
1.0	0.38	0.58	0.66	0.71	0.74	0.76	0.80	0.82	0.85	0.87
1.1	0.42	0.64	0.73	0.78	0.82	0.84	0.88	0.90	0.94	0.96
1.2	0.47	0.71	0.80	0.86	0.90	0.92	0.96	0.99	**1.03**	**1.05**
1.3	0.51	0.77	0.87	0.93	0.97	**1.00**	**1.04**	**1.07**	1.11	1.14
1.4	0.56	0.83	0.94	**1.01**	**1.05**	1.08	1.13	1.16	1.20	1.23
1.5	0.60	0.90	**1.01**	1.08	1.13	1.16	1.21	1.24	1.29	1.32
1.6	0.64	0.96	1.09	1.16	1.21	1.24	1.29	1.32	1.38	1.41
1.7	0.69	**1.02**	1.16	1.23	1.28	1.32	1.37	1.41	1.46	1.49
1.8	0.73	1.08	1.23	1.31	1.36	1.40	1.45	1.49	1.55	1.58
1.9	0.77	1.15	1.29	1.38	1.44	1.48	1.54	1.58	1.64	1.67
2.0	0.82	1.21	1.36	1.45	1.51	1.56	1.62	1.66	1.72	1.76
2.1	0.86	1.27	1.43	1.53	1.59	1.64	1.70	1.74	1.81	1.85
2.2	0.90	1.33	1.50	1.60	1.67	1.72	1.78	1.83	1.90	1.94
2.3	0.95	1.39	1.57	1.68	1.74	1.79	1.86	1.91	1.98	2.03
2.4	0.99	1.46	1.64	1.75	1.82	1.87	1.95	1.99	2.07	2.11
2.5	**1.03**	1.52	1.71	1.82	1.90	1.95	2.03	2.08	2.16	2.20

For example, for a sample size of 30, C_{pk} of 1.3 would need to be calculated to have a 95% confidence that the true but unknown C_{pk} is 1.0 or greater.

例如，一个样本容量为 30，Cpk 为 1.3 的过程，在置信度 95%，计算得出的 Cpk 为 1.0 或更大，这并不确定。

One of the generalized formulas for the Cpk confidence interval is:
C_{pk} 置信区间的通用计算公式：

$$LCI= C_{pk}-Z_{1-a} *SQRT(1/9*n)+(C_{pk})^2/2*(n-1)))+1/30*SQRT(n))$$

5.6.3 Cpk for Several Groups 多组的Cpk

In this example, the short-term variability or variability within the group is used to find C_{pk}. This does not take into account the variability of different groups. This C_{pk} assumes that the group means are the same. Thus, the C_{pk} found here is as good as it will be.
在这个例子中，利用组内的短期变化或变异来寻找 C_{pk}。这没有考虑到组间的差异，这是在假设组间是没有差异的情况下得到的 C_{pk}，因此，这样得出的 C_{pk} 都很好。

Step 1 Collect the data. Here, six groups of five values are taken over time. See Table 5.6.3-1 for the data and summaries.
步骤 1 这里收集 6 组数据，每组 5 个值。见表 5.6.3-1

Table 5.6.3-1 C_{pk} for Several Groups 多组数据的 C_{pk}

Value	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	
1	94.1	93.1	91.2	93.9	90.6	92.4	
2	102.7	95.2	98.1	101.6	96.2	101.3	
3	101.9	100.2	96.3	103.1	99.0	101.0	
4	103.3	98.5	93.8	99.8	97.7	99.1	
5	100.5	102.6	104.8	99.4	98.6	96.5	
Range	9.1400	9.4512	13.5881	9.223	8.4423	8.9232	Average Range 9.7946
Average	100.4930	97.9069	96.8425	99.5611	96.4329	98.0678	Grand Average 98.2174

Step 2 Calculate the average and the variability estimate
步骤 2 计算平均值和变异估计

The grand average of the data is 98.2174.
平均值为 98.2174
The average range is 9.7946. The sample size is 5.
变异平均值为 9.7946，样本量为 5。
The standard deviation is estimated by dividing the average range by d2 from Table 5.6.2-4.

标准偏差是通过变异平均值除以 d2 进行估计。d2 取值见表 5.6.2-4。

Table 5.6.3-2 For d2

Sample Size	d2
2	1.13
3	1.69
4	2.06
5	2.33
6	2.53
7	2.70
8	2.85
9	2.97
10	3.08
11	3.17
12	3.26
13	3.34
14	3.41
15	3.47

For a sample size of 5, d2 is 2.33
如样本量为 5 时 d2 取 2.33。
The standard deviation is 9.7946/2.33 = 4.2037
标准偏差=9.7946/2.33 = 4.2037

Step 3 Calculate Cpk for several groups
步骤 3 计算多组 Cpk 值

The example specification criteria are 90.0%-100.0%
例子的标准为 90.0%-100.0%（我觉得是印刷错误，应为 110%）

C_{pl}= (98.2174-90.0)/ (3*4.2037) = 0.65

C_{pu}= (110.0-98.2174)/ (3*4.2037) = 0.93

C_{pk}= 0.65

Step 4 Based on this data, the process is probably not capable of meeting the specifications, even in the short term. It is possible that sample selection is not adequate and that the true process C_{pk} is greater than 1.0, so more data would have to be collected to get a better estimate of the true value. Without the extra samples, the only conclusion is that the process is not capable of reliably meeting specifications.
步骤 4 从这些数据可以看出，在短期内这个过程并不能达到要求。也有可能是该过程的真实 Cpk 值是大于 1 的，但由于样本选择的不够充分造成了这个结果，因此需要收集更多的数据来估计这个过程真实的 C_{pk} 值。如果没有其他例子，那么对该过程下的结论就是不能满足要求。

5.6.4 Example 3, Ppk for Several Groups 例3，多组的Ppk值

In this example, the long-term variability or total variability is used to find Ppk. This takes into account the variability within groups and the variability from group to group. This Ppk does not assume that the group means are the same. Thus, the Ppk here is a realistic estimate of future long-term capability.
在这里，利用长期的变异或总的变异来求 Ppk 值。这需考虑组内差异和组间的差异。Ppk 的计算并不是假设组间没有差异，因此，Ppk 是对将来长期过程能力指数的估计。

Step 1 Collect the data. Here six groups of five values are taken over time. See Table 3 for the data.
步骤 1 收集数据。这里还采用表 3 的数据

Step 2 Calculate the average and the variability estimate
步骤 2 计算平均值和变异估计

The grand average of the data is 98.2174.
平均值为 98.2174
The standard deviation of all of the data taken as one group is 3.9599.
把所 6 组中所有数据当成一个组来计算标准偏差得出结果为 3.9599。

Step 3 Calculate P_{pk}
步骤 3 计算 P_{pk}

P_{pl}= (98.2174-90.0)/ (3*3.9599) =0.69
P_{pu}= (110.0-98.2174)/ (3*3.9599) =0.99
P_{pk}=0.69

Step 4 Based on this data, the process is probably not capable of meeting the specifications in the long term. It is possible that sample selection is not adequate and the true process P_{pk} is greater than 1.0, so more data would have to be collected to estimate the true value. Without the extra samples, the only conclusion is that the process is not capable of reliably meeting specifications.
从这些数据可以看出，该过程能力不能满足将来长期的要求。也有可能是该过程的真实 Ppk 值是大于 1 的，但由于样本选择的不够充分造成了这个结果，因此需要收集更多的数据来估计这个过程真实的 Cpk 值。如果没有其他例子，那么对该过程下的结论就是不能满足要求。

5.7 Exponentially Weighted Moving Area Charts (EWMA) 指数加权移动区域图（EWMA）

5.7.1 Technical Details 计算细节

The EWMA value is calculated[6] as $EWMA_t = \lambda X_t + (1-1)\ EWMA_{t-1}$ for t = 1, 2, ..., *n*. where $EWMA_t$ is the moving average of the historical data:
EWMA 值由 EWMAt 计算。EWMAt=λX t+(1-l) EWMAt-1,, t=1,2,…,n. EWMAt 为历史数据的移动平均值。

• X_t is the observation at time t
X_t 为次数 t 时的观察值

• *N* is the number of observations to be monitored, including $EWMA_0$
N 被监控的观察次数，包括 $EWMA_0$

• The primary weighting factor is represented as λ (lambda). This can be described as the portion of the current point that will be added to the prior average. Each successive EWMA point is the sum of the weighted current data point and the prior EWMA point.
一级加权因子用 λ 代表。这可描述为当前点呗加到之前平均值的部分。每次连续的 EWMA 点是加权当前数据点和之前 EWMA 点的和。

• λ is a constant that determines the depth response time of the EWMA. This value is a proportion so the values must be between 0 and 1, with typical values 0.05-0.4, depending on the amount of dampening desired (smaller λ=more dampening). Smaller values for λ can detect smaller changes in mean, but will increase the time to respond to shifts.
λ 是测定 EWMA 响应次数的定值。这个值是一个比率，因此在 0 到 1 之间，典型值是 0.05-0.4，取决于所需的阻尼值。更小的 λ 值能检测到更微小的变更，但将增加轮回的次数。

5.7.2 Calculation Example 计算实例

Simple step-change example with no process noise with λ= 0.4
简单的 λ=0.4，没有过程噪音的变更举例

Table 5.7.2-1 Step-Change Example (No process noise) 表 5.7.2-1 变更举例（没有过程噪音）

Time(t)	Date	Method	EWMA
1	10	First EWMA point is a special case, if available use Target or Process average, otherwise use first data point. 第一个EMEA 点是特殊情况，如适用，使用目标值或工艺平均值，否则使用第一个数据点	10
2	10	10*0.4 + 10.00*（1-0.4）	10.00
3	11	10*0.4 + 10.00*（1-0.4）	10.40
4	11	10*0.4 + 10.40*（1-0.4）	10.64
5	11	10*0.4 + 10.64*（1-0.4）	10.78
6	11	10*0.4 + 10.78*（1-0.4）	10.87
7	10	10*0.4 + 10.87*（1-0.4）	10.52
8	10	10*0.4 + 10.52*（1-0.4）	10.31
9	10	10*0.4 + 10.31*（1-0.4）	10.19
10	10	10*0.4 + 10.19*（1-0.4）	10.11

Example Calculation
At t=1, if there is no process average, the first observation is transferred. If a process average or target has been established, it may be used as a starting point for the trend.
结论
当 T=1 时，如果没有工艺平均值，第一个观测值被转移。如果工艺平均值或目标值已被建立，可作为趋势的起始点。

Example Calculation
EWMA for time 3 is
Observation (t=3)(11)*Lambda (0.4) + EWMA (t=2) * (1-Lambda)
结论
次数 3 时的EWMA是观测值（ t=3 ）(11)* λ (0.4)+EWMA(t=2)*(1-λ)

5.7.3 Control Limits 控制限度

In order to calculate control limits, there should be established expectation for process mean ($u_{process}$) and standard deviation ($S_{process}$).
为了计算控制限度，应建立工艺平均值($u_{process}$)和标准偏差（$S_{process}$）加权平均为了减少偏差。

The weighted averaging tends to reduce deviation. The standard deviation of the EWMA statistic is Control Limits (assuming ±3 sigma intent). For low numbers of samples, the control limits are somewhat narrower and an alternate formula may be applied.
EMEA 统计的标准偏差是控制限（预计值±3sigma）。对于较少样品数，控制限较窄，选择公式可供应用。

$$S_{EWMA} = S_{process}\sqrt{\frac{\lambda}{2-\lambda}}$$

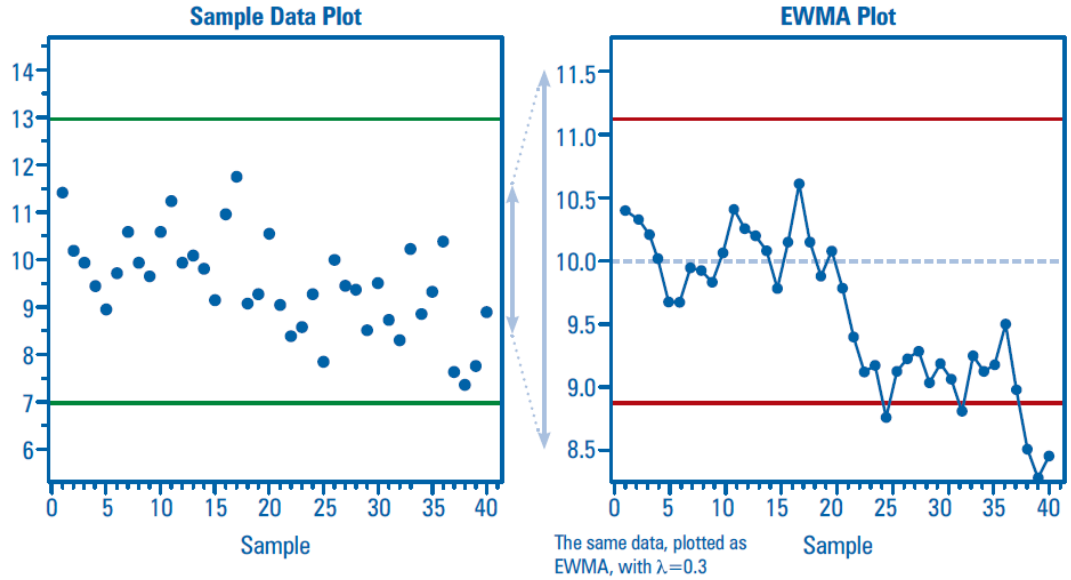
$$UCL_{EWMA} = \mu_{process} + 3 \times S_{process} \times \sqrt{\frac{\lambda}{2-\lambda}}$$

$$UCL_{EWMA} = \mu_{process} - 3 \times S_{process} \times \sqrt{\frac{\lambda}{2-\lambda}}$$

5.7.4 Example 实例

A sample data set was prepared with an expected mean of 10 and standard deviation of 1, randomly distributed. The mean of this simulated process contains a shift. The same data is plotted with both a conventional data plot (run chart), and the EWMA chart. The EWMA was configured with $\lambda = 0.3$.
一个抽样数据集设定预期平均值为 10，标准偏差为 1， 随机分布。该模拟过程的平均值包含了一个移位。同时使用常规数据图（趋势图）和 EWMA 指数加权移动平均图描绘相同的数据，用λ =3 设置 EWMA。

Figure 5.7.4-1 Sample Random Distribution Plots



5.7.4.1 Interpretation of Example (例子解读)
Data Plot- If individual results are plotted, no points fall outside the ± 3 standard deviation limits。

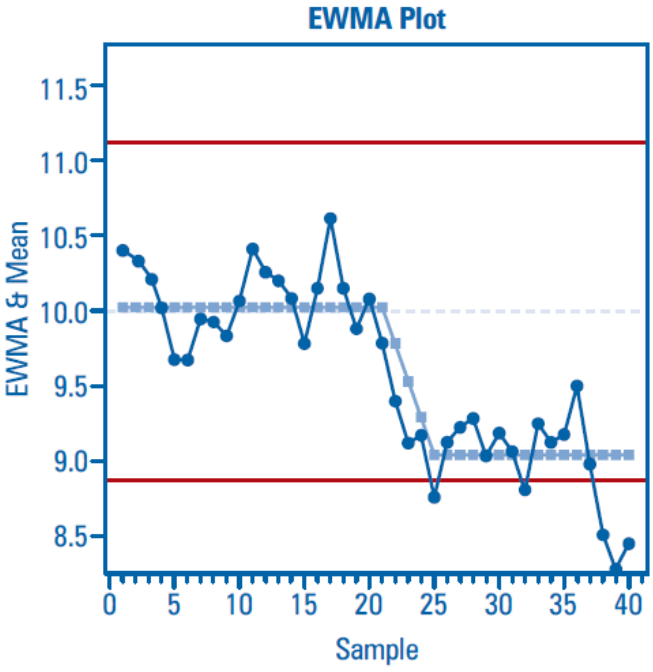
数据图-如果绘制个别结果， 没有点落在±3 的标准偏差之外。

EWMA Plot - The control limits of the EWMA are exceeded several times, annunciating that this process average has shifted. Although the control limit is first exceeded at point 25, the review of the process performance should extend back to the time when the trend appears to deviate from the former average. The investigation question in this case would be, "What changed in the process sometime between sample 20-25 that continues to affect sample since then?" The investigation question is not "What is different about points 25, 32, 38-40?"
EWMA 指数加权移动平均图- 超出 EWMA 控制限度多次，指示过程平均值已移动。尽管第一次超出控制限是 25 这个点上，然而对工艺性能的回顾应该延伸到趋势表现出要偏离原来平均值的时候。在这种情况下，调查问题应为："在样本 20-25 中间某个时间点发生了什么改变持续影响到自此以后的样本？调查问题不应该是 "点 25，32，38-40 有什么不同？

The reduction in the variability of individual points allows the vertical axis to increase in resolution, and the approximate average at various time periods is readable directly from the chart (in the example, the process mean started at 10, and started drifting downward at sample 22, dropping to 9 at sample 25).
单个点可变性的减少允许纵轴分辨率的增加，并且不同时期的近似平均值可以直接从图上读出来。（在本例中，过程平均值从 10 开始，从 22 开始向下移动，在样本 25 处降至 9）。

The figure below shows the same chart printed with the underlying mean drift of the simulated data made visible.
下图展示了一张相同的图表，可明显的看出模拟数据潜在的平均值移动。

Figure 5.7.4.1-1 EWMA Plot (UCL & LCL)



Notice that even though the mean shift is steady, points 25-40 intermittently fall in or out of the control limit. There is still randomness to the detection. Had the process shift been larger, the detection would have been more definitive. Had λ been smaller, the control limits would have been tighter, and the detection

would have been more definitive, but later. Further discussion of the trade-offs in selection of λ is beyond the scope of this document.
可以注意到即使均值平移很稳定，点 25-40 仍会间歇的落在控制限内外。检测仍然存在随机性。如果工艺偏离比较大的话，检测应更具限定性。如果 λ 值较小的话，控制限应该更严格，检测应该更限定，但要晚于控制限的确定。关于 λ 值取舍的进一步讨论不在本文件范围内。

5.8 CuSum Charts 累积和图

CuSum charts plot the cumulative sum of deviation from a target value.
累积和图表描绘了目标值偏差的累积和。

For individual data points, the formula is
对单一的数据点而言，公式如下：

$$C_j = \sum_{i=1}^{j} (x_i - \mu)$$

C：value for the CuSum Chart; x = measured parameter; μ= mean
C：累积和图表值；X=测量的参数；μ=平均值。

5.8.1 Example Calculation 实例计算

The expected value for the process in this example is 10.0. The mechanics of the calculation are illustrated in **Figure 5.8.1-1**. The resultant plots are shown in **Figure 5.8.1-2**.
该过程的预期值是 10.0。运算过程如图 5.8.1-1 所示，结果见图 5.8.1-2。

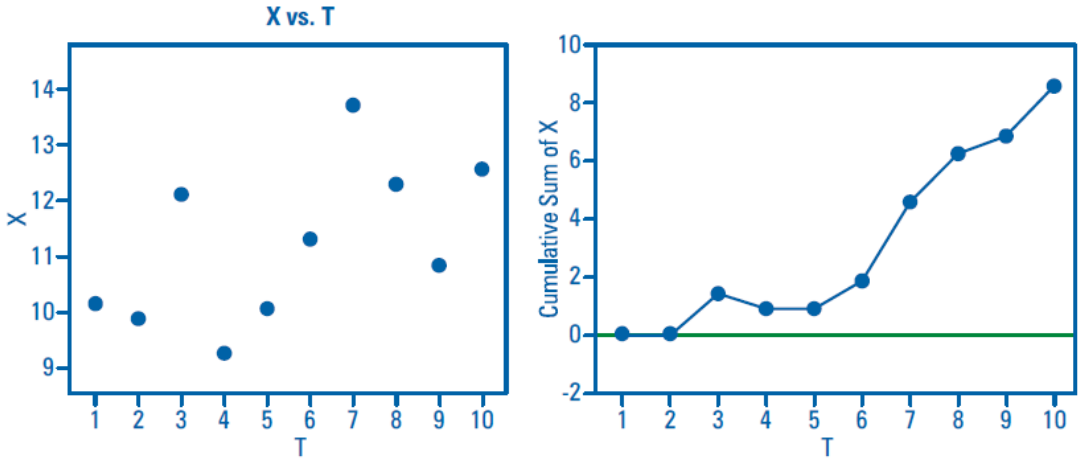
Figure 5.8.1-1 Example Calculation 图 5.8.1-1 实例计算

Time (t)	Data	Method		CUSUM
1	10.12	10.12-10.00		0.12
2	9.85	9.85-10.00	+ 0.12	-0.03
3	12.10	12.10-10.00	+ -0.03	2.08
4	9.22	9.22-10.00	+ 2.08	1.29
5	10.04	10.04-10.00	+ 1.29	1.34
6	11.27	11.27-10.00	+ 1.34	2.61
7	14.73	14.73-10.00	+ 2.61	6.34
8	13.30	13.30-10.00	+ 6.34	8.63
9	11.81	11.81-10.00	+ 8.63	9.44
10	13.56	13.56-10.00	+ 9.44	12.00

Example Calculation
CUSUM for time 3 is Observation $_{(t=3)}$ (12.10) – Expected Value (10.0) + CUSUM $_{(t=2)}$

实例计算
第 3 次的 CUSUM 是观测点$_{(t=3)}$（12.10）－预期值(10.0) + CUSUM $_{(t=2)}$

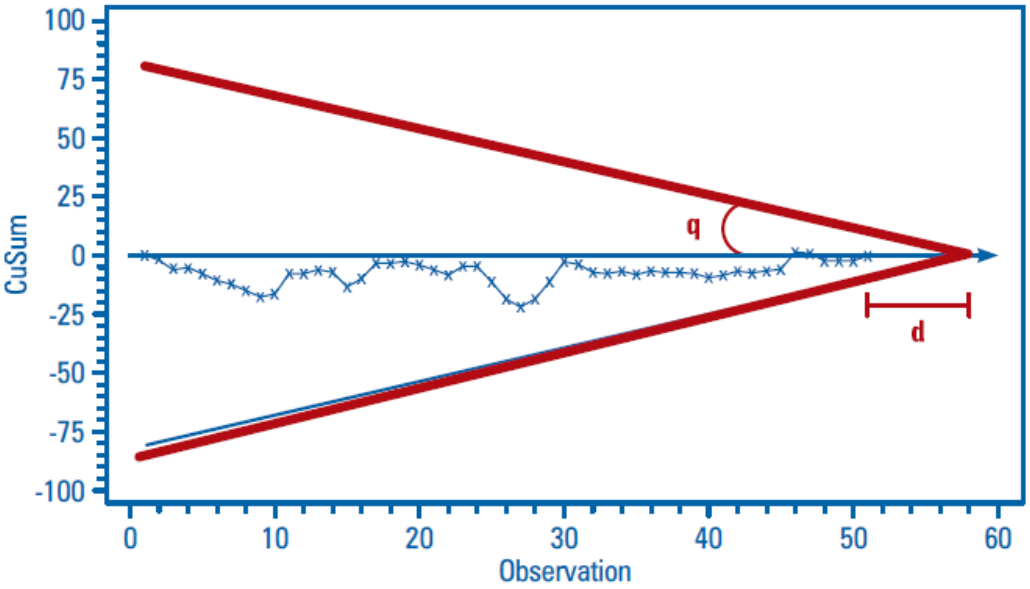
Figure 5.8.1-2 X-bar Chart vs. CuSum Chart 图 5.8.1-2 X-bar 图表 vs. CuSum 图表



If the process is in a state of statistical control around the expected value of 10.0, the CuSum Chart would vary around zero which represents the horizontal line.
如果该过程处于统计受控状态，在预期值 10.0 上下，累积和（CuSum）图会在水平线即 0 值附近浮动。

A V-mask is plotted to indicate whether or not the process is in a state of statistical control (**Figure 5.8.1-3**). This is similar in function to a running statistical t-test. It determines whether or not the process is discernibly different at any point in time. This V-mask is placed at a distance d. The opening of the mask is drawn at an angle of ±q. The manual calculation of these values is outside the scope of this document.
V-mask 能够显示出该过程是否处于统计受控状态（图 5.8.1-3），在功能上和进行统计学的 t-test 相似，并能够及时判断出过程是否在任意点有可辨别出的不同。V-mask 放置在一定的距离 d。Mask 的开口角度是±q。这些值的手动计算过程不在本文件的范围内。

Figure 5.8.1-3 CuSum Chart with V-mask 图 5.8.1-3 含有 V-mask 的累积和图表



For further reading, see ISO/TR 7871:1997: Cumulative sum charts – Guidance on quality control and data analysis using CuSUM techniques. This document provides the principles for CuSum charting and includes guidance on the preparation and interpretation of CuSum charts using basic decision rules.
进一步阅读参考，见 ISO/TR 7871:1997：累积和图—运用累积和技术进行质量控制和数据分析的指南。这个文件提供了绘制累积和图表的原则，并包括了制备和运用基本决策规则解析 CuSum 图表的指南。

5.8.2 Details of Principles 具体原则

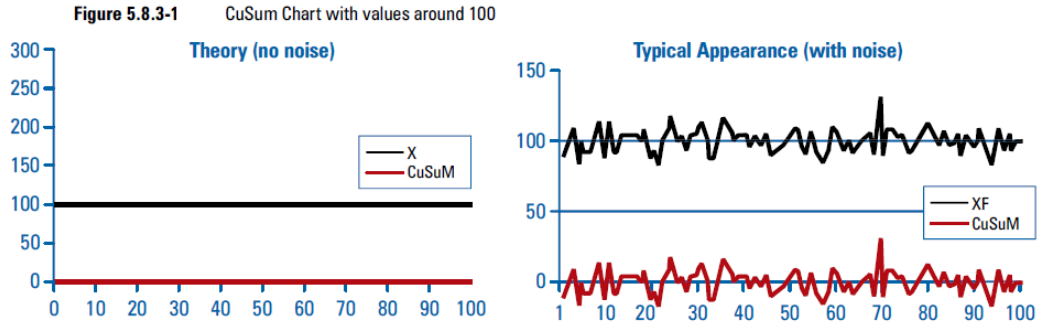
CuSum charts monitor the available data by plotting the cumulative sum of deviations from a fixed value (e.g., specification, average, and target). They incorporate the past history of the monitored process into the plotted points for the selected parameter. As a result, greater sensitivity and shorter run length than those in x-bar or I-charts are achieved. Small shifts to the process mean are visible as a change in slope that indicates when the change occurred. CuSum charts are usually plotted with a V-mask. This provides reference slopes to annunciate that a change in mean is significant.
累积和图表通过绘制一个固定值（例如，质量标准、平均值、目标值）的偏差的计数积累来监测数据。这样比 x-bar 或 I-图表的灵敏性更好，运行时间也更短。过程平均数的小变化表现为斜率的变化，可以看出变化发生的时间。累积和图表通常带有一个 V-mask，能提供参照斜率来说明平均值的变化非常明显。

5.8.3 Interpretations Worked in Parallel with Theory/Principles 与理论/原则并行的解释

The mathematical process to construct a CuSum Chart has advantages to detect deviations in the process by taking into account the knowledge of the past. To understand basic appearance of graphs see some examples without the V-mask：
用数学过程建立累积和图表具有能够利用先前的知识探测过程偏差的优势。可以学习一些不带 V-mask 的例子来理解图表的基本形式。

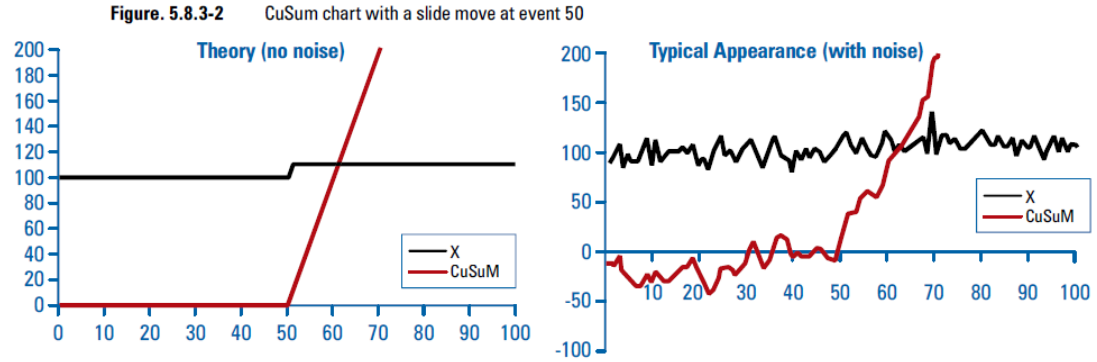
Assume the values (x) are determined around 100. The CuSum chart would show some ‘noise’ (**Figure 5.8.3-1**).
假设值（x）大约为 100。累积和图表会显示一些“噪音”（图 5.8.3-1）。

Figure 5.8.3-1 CuSum Chart with values around 100 数值约为 100 的累积和图表



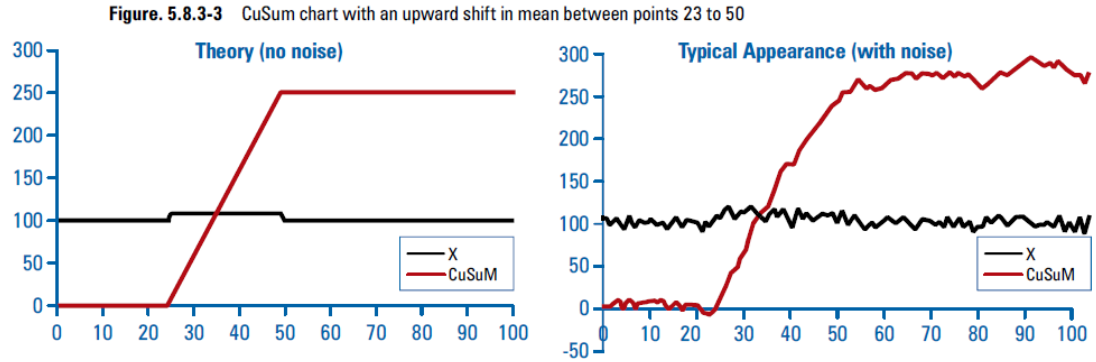
If the values (X) at point 50 slight moves up, the CuSum chart answers with a rising graph **(Figure 5.8.3-2).** The CuSum chart shows a significant change in slope that is far more apparent than in the data plot.
假设值（X）在 50 这个点时缓慢上升，累积和控制图以上升曲线的方式显示（图 **5.8.3-2**）。累积和控制图坡度的显著变化比数据图中更加明显。

Figure 5.8.3-2 CuSum chart with a slide move at event 50 累积和控制图在 50 处的波动



If the values (X) change for a brief period and then return to the prior average, the CuSum chart will show a brief slope and then return to parallel when the set point (100) is re-achieved. **(Figure. 5.8.3-3)**
若值（X）在一个短周期内改变后重新回到之前的平均值，当设定值重新达到 100 时，累积和控制图会显示一个短的坡度变化后，趋于平稳。

Figure. 5.8.3-3 CuSum chart with an upward shift in mean between points 23 to 50
在 23-50 点处，累积和控制图平均值向上偏移



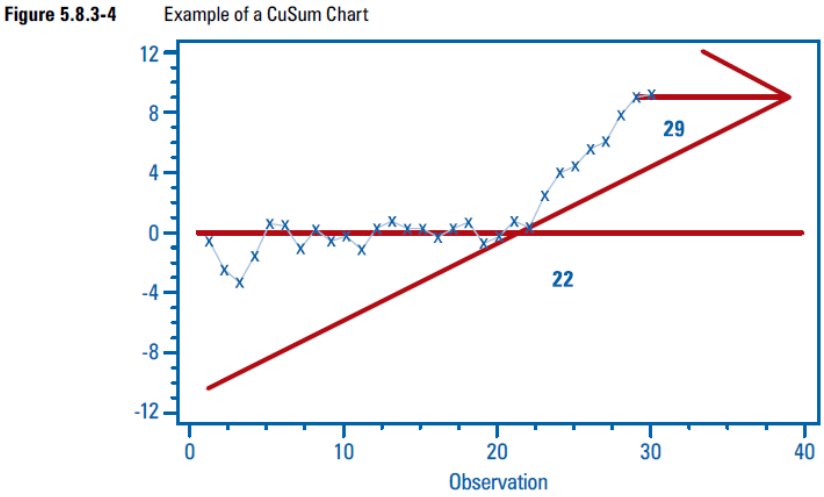
For interpretation of a CuSum chart including a V-mask, the two principles apply:
以下两原则用于阐释使用 V 型模板法的累积和控制图：

- The process is in a state of statistical control if the entire history lies within the opening of the V-mask
  如果整个过程在 V 型模板的开端内，则这个过程是在统计控制状态。

- The process average is statistically different if any point lies outside the V-mask
  如果过程均值任一点位于 V 型模板之外，则有统计学差异。

The example given shows a full CuSum chart including a V-mask (**Figure. 5.8.3-4**). The V-mask is positioned in front of the CuSum at the 29 event. The point at time the 22 event goes outside the V-mask. This indicates a statistically detectable difference in mean. The departure from "statistical control" does not mean that the process itself is out of control or unacceptable. The interpretation is that the process mean appears to have shifted upwards as the slope of the CuSum is positive.
如表 5.8.3-4 所述说明用 V 型模板的累积和控制图，在 29 样本中 V 型模板位于累积和控制图的前段。在 22 样本中的点不在 V 型模板中，在均值上为统计学上的可检测差异。违背统计控制并不意味着过程不受控制或不能接受，而是说明当累积和控制图的斜率为正值时过程均值显示为向上偏移。

Figure. 5.8.3-4 Example of CuSum 累积和控制图



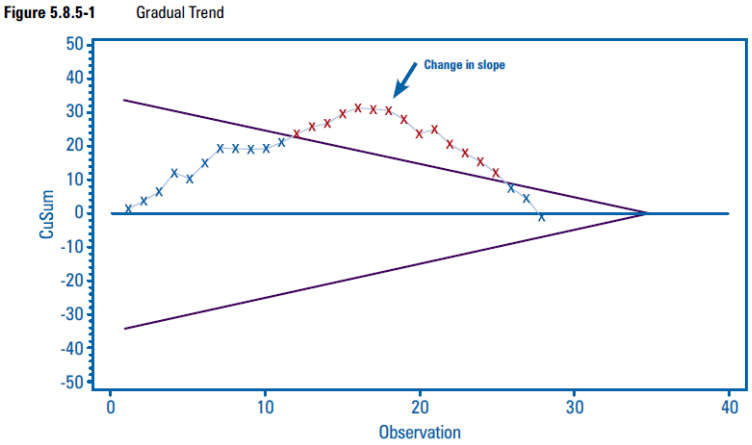
5.8.4 Implementation of CuSum Charts 累积和控制图的执行

To implement CuSum charts, a data set with a target or average value is needed. The data can be obtained by manual measurements (e.g., manual In Process Check (IPC) tests, yield) or automatically (e.g., LIMS systems, PAT application). The data are mapped (e.g., usually in an Excel spreadsheet) and the CuSum chart is monitored (e.g., in MS-Excel http://www.qimacros.com/qiwizard/cusum-chart.html) or by statistical programs.
执行累积和控制图，需要设置一个指标或平均值数据，这数据能通过手动测量（如手动过程检测试验，收率）或自动测量（如 LIMS 系统，PAT 申请）得到。这数据被标识（如通常在 excel 扩展表中）和累积和控制表被监测（如在 MS-Excel，http://www.qimacros.com/qiwizard/cusum-chart.html)或通过统计程序。

5.8.5 Example: Gradual Trend 实例：渐变趋势

If the curve twists off outside the V-mask without a sharp point change in slope, the data are gradually trending. This trend is statistically relevant if it is outside the V- mask (see after value 11 in the **Figure 5.8.5-1).**

Figure 5.8.5-1 Gradual Trend 渐变趋势



There is a continual trend without a crack.
此为没有断裂的连续趋势。

5.8.6 Preventative Action Before Failure Occurrence 失败发生前的预防措施

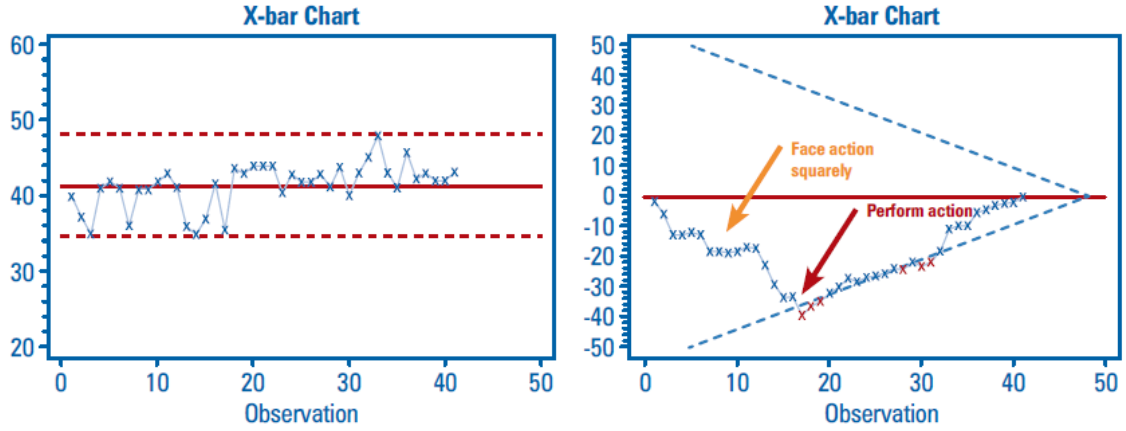
After observation eight, the CuSum chart shows a raise. Also this result of the IPC sample was available about 5 hours later, and other samples already were taken so a side adjustment of a parameter could have been performed. As a result, the process drift could be controlled before a statistically significant effect was detected by other means.
观察 8 后，累积和控制图显示为增长，大约 5 小时后可得到此中间体测试样品的结果，其它的样品也可通过将一参数进行单侧校正获得同样结果。因此，在通过其它均值检测到一个统计学显著差异之前能控制过程偏移。

5.8.7 Example: For Process Optimization 实例：用于过程优化

Sometimes processes are not running in a distinct distribution around the target value. Lot-by-lot incremental adjustments of a specific critical process parameter have been monitored with following up on a CuSum chart. Raises and plateaus have been controlled until the graph goes to a straight line (**Figure 5.8.7-1**).
有时在目标值范围内的清晰分布中过程不会运行。逐批增加用下列累积和控制图检测的某一关键过程参数调整。增长期和平稳期一直被控制到图表成为一条直线。

Figure 5.8.7-1 For Process Optimization 用于过程优化

Figure 5.8.7-1 For Process Optimization



The effect can be revisited in the x-bar chart afterwards.
这影响 x-bar 表中能回归。

5.9 Sampling 抽样

The basic process for developing a sampling plan is listed below. Further details are outside the scope of this document. Please consult an appropriate resource.
下面列出的是制定抽样计划的基本过程。更详细的内容在此文件范围外，请翻阅合适的资源（文献）。

Step 1 - Determine the purpose for the inspection.
步骤 1-确定检验目的。

Step 2 - Determine and list each quality characteristic by name and description.
步骤 2-按照名称和说明确定并列出每个质量属性。

Step 3 - Specify to which product unit each quality characteristic applies and which the test is to be made. Specify the product unit associated with each quality characteristic and which tests are to be applied.
步骤 3-指定每一质量参数应用的产品单位并被测试。指定与每一质量参数相关联的产品单位并进行测试。

Step 4 - Develop and specify the method to be used for testing the product for conformance.
步骤 4-建立并列出用于一致性产品检验方法。

Step 5 - Determine and specify the criteria for conformity for each quality characteristic (give detailed descriptions).
步骤 5-确定并列出符合每个质量属性的标准。（详细说明）

Step 6-Determine and list the classification of nonconformities that affect a unit of product.(This refers to degree of Importance/severity of the nonconformity）.This is generally a result of a risk assessment.
步骤 6-确定并列出影响产品单元不合格的类别（这关系到不合格程度的严重性）。这通常是一个风险评估的结果。

Step 7 - Determine the appropriate index quality level (AQL， RQL) on which to base the sampling

procedures for each nonconformity classification.
步骤 7-确定不合格类别基于抽样程序的质量水平（AQL， RQL）的合适指标。

Step 8 - Obtain appropriate information on lot formation.
步骤 8-在批的形成上获得合适的数据。

Step9-Determine what method of sampling will be used for each nonconformity classification, nonconformity grouping， or product unit distinction(to obtain representative sample)
步骤 9-确定什么样的抽样方法，将用于每个不合格分类，不合格分组，或产品单元的差别（获得有代表性的样品）

步骤 10-Determine the type of sampling that will be used for each nonconformity classification, nonconformity grouping, or product unit distinction (e.g.， single， double， etc.). The type of sampling Selected is generally based on whether the efficiency gained by the various sampling types justifies the additional complexity of administering the plans.
步骤 10-确定将使用每个不合格分类、不合格分组或者产品单元的差别的抽样类型，（例如，单、双等）。采样的类型选择一般原则是根据是否由不同采样类型获得的效率为额外的管理计划的复杂性。

Step 11 - Develop the sampling plan and include:
步骤 11-建立的取样计划包括：

Provisions for disposition of rejected lots (e.g.， 100% inspection)
对于拒绝批的处理规定。（例如：100%检验）
Provisions for resubmission of reworked product
对于返工产品的重新提交规定。

5.9.1 Example实例

Suppose a vendor supplies empty vials in a lot size of 250，000. The drug manufacturer decides to implement a sampling plan for either accepting or rejecting the entire lot. The drug manufacturer and the vendor agree that the AQL is 1.0% and the RQL is 2.5% for a given defect.
假设供应商提供的空瓶子的批量是 250，000 个，药品生产企业决定为了接收或者拒绝整批而实施一个取样计划。药品生产企业和供应商同意 AQL 为 1.0%或者对于一个给定的缺陷 RQL 为 2.5%

Stated producer's risk (Alpha) 二 5% and consumer's risk (Beta) = 2.5%
规定生产企业的风险=5%或者消费者的风险（批）=2.5%

Lot size: 250，000
批量：250，000
Acceptable Quality Level (AQL) =1.0%
可接受限=1.0%
Producer's Risk (Alpha) =5%
生产企业风险=5%

Rejectable Quality Level (RQL，LQ，or LTPD) = 2.5%

参考限（批量质量或者批次运行次品率）=2.5%
Consumer's Risk (Beta) =2.5%
消费者的风险（整批）=2.5%
Generated Plan:
生成的计划：
Sample Size =985
取样量=985
Acceptance Number =15
接受数量=15
Accept lot if defective items in 985 sampled≤15;otherwise reject
如果在 985 个样品中有缺陷项目的个数不大于 15 则可以接受，否则拒收。

Probabilities from this plan are listed in Table 5.9.1-1.
这个计划的概率在表 5.9.1-1 列出

Table 5.9.1-1 Characteristics of Example Test Plan 实例测试计划特征

Percent Defective	Probability of Accepting	Probability of Rejecting	AOQ	ATI
1.0	0.957	0.043	0.953	11667
2.5	0.025	0.975	0.062	243794

缺陷率	接受概率	拒收概率	平均抽样质量	平均检验数量
1.0	0.957	0.043	0.953	11667
2.5	0.025	0.975	0.062	243794

AOQ——Average outgoing Quality(平均抽样质量)
Approximates the relationship between the quality of the incoming material and the quality of the outgoing material，assuming that the rejected lots will be 100% inspected and defective items will be reworked and inspected again (rectifying inspection).
假设购进材料的质量和抽样材料的质量两者之间近似一致，假如拒收批将被 100%检出并且不合格品将被返工，再次被检出（纠正检验）。

ATI—Average Total Inspection 平均检验数
Approximates the relationship between the quality of the incoming material and the number of items that need to be inspected, assuming that rejected lots will be 100% inspected and defective items will be reworked and inspected again(rectifying inspection).
接近来料的质量和需要检查的项目数之间的关系，假设拒收批次将 100%被检出并且不合格品将进行返工，并再次检查（纠正检验）

For each lot of 250,000 empty vials , randomly select and inspect 985 of them. If there are greater than 15 defectives among these 985 empty vials, the entire lot should be rejected. For 15 or less defective empty vials, accept the entire lot.
每批 250000 个空瓶，随机选择和检查 985 个。若 985 个空瓶中超过 15 个不合格，则整批应予以拒绝；若小于等于 15 个，则接受。

In this example (operating characteristic chart curve in figure 5.9.1-1),the probability of acceptance at the AQL(1.0%)is 0.957 and the probability of rejecting is 0.043.The sampling plan is based on the expectation that lots with 1.0% defective units would be accepted approximately 95% of the time. The probability of accepting at the RQL(2.5%) is 0.025 and the probability of rejecting is 0.975.
在这个例子中（工作特性图曲线图 5.9.1-1），接受的概率在 AQL（1.0%）是 0.957，拒绝的概率是 0.043。抽样计划是基于期望整批中 1.0%次品将被接受大约 95%时。接受概率在 RQL（2.5%）是 0.025，拒收的概率为 0.975。

Figure 表 5.9.1-1 OC Chart Curve 曲线图

Operating Characteristic (OC) Curve
工作特征图
Sample Size=985， Acceptance Number=15
样品量=985 接收数 15