Setting and Measuring Quality Objectives

The concept of quality objectives is very important to a Quality Management System (QMS), because it converts the broad statements of the Quality Policy into specific and concrete targets and actions. Solid quality objectives can help create an effective QMS.

Medical Device Quality Management Systems
The two most common medical device quality management systems are 21 CFR Part 820, for use in the US, and ISO 13485:2003, an international standard. Many countries adopt ISO 13485:2003 as a national standard. One exception is the European Union's EN ISO 13485:2012 which documents some areas where the product directives and the international standard do not align. However, none of misalignments involve the quality policy or quality objectives.

For FDA QSR, the requirement is in §820.20(a) Management responsibility – Quality policy.
"Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization."

For ISO 13485:2003, the basic requirements are in Clause 5.3 Quality policy.
"Top management shall ensure that the quality policy
a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability."

In addition, 5.4.1 Planning – Quality objectives requires, "The quality objectives shall be measurable and consistent with the quality policy".

Quality Policy
The Quality Policy sets the stage for the quality objectives. A very simple quality policy will illustrate the linkage. QSR, unlike ISO 13485:2003, doesn't have any requirements for the statement of the Quality Policy, so a very simple Quality Policy for Acme Widgets could be:

Acme Widgets provides good stuff on time!

Adding the additional requirements from ISO 13485:2003 we can expand the Quality Policy.

Acme Widgets provides good stuff on time, complies with requirements, and maintains the effectiveness of the QMS!

Metrics
Quality objectives need to be measurable; an operational definition is a common tool. The metric helps communicate the objectives to the employees and helps Management Review determine if they are successful.

Quality objectives commonly use three kinds of metrics.

- *Effectiveness* measures the ability of a process to achieve its intended result
  ISO 9000:2005, 3.2.14 – effectiveness means the extent to which planned activities are realized and planned results achieved

- *Efficiency* measures the resources required for a process to achieve its intended result
  ISO 9000:2005, 3.2.15 – efficiency means the relationship between the result achieved and the resources used

- *Cycle time* measures the duration of a process to meet its intended result

Setting Objectives
Objective #1: Nonconformance rate in the plant (supports good stuff)
Objective #2: Complaint rate for shipped products (supports good stuff)
Objective #3: Complaint corrective action closure time (supports good stuff)
Objective #4: On time delivery rate (supports on time)
Objective #5: Requirement compliance rate (supports regulatory compliance)
Objective #6: Regulatory compliance activity effort (supports regulatory compliance)
Objective #7: Audit nonconformance rate (supports QMS effectiveness)
Objective #8: Audit nonconformance corrective action closure time (supports QMS effectiveness)
Objective #9: Audit nonconformance corrective action closure effort (supports QMS effectiveness)

The table below shows the metric type appropriate for each Objective.

Objective	Metric Type		
	Effectiveness	Efficiency	Cycle time
Nonconformance rate in the plant	Yes		
Complaint rate for shipped products	Yes		
Complaint corrective action closure time			Yes
On time delivery rate	Yes		
Requirement compliance rate	Yes		
Regulatory compliance activity effort		Yes	
Audit nonconformance rate	Yes		
Audit nonconformance corrective action closure time			Yes
Audit nonconformance corrective action closure effort		Yes	

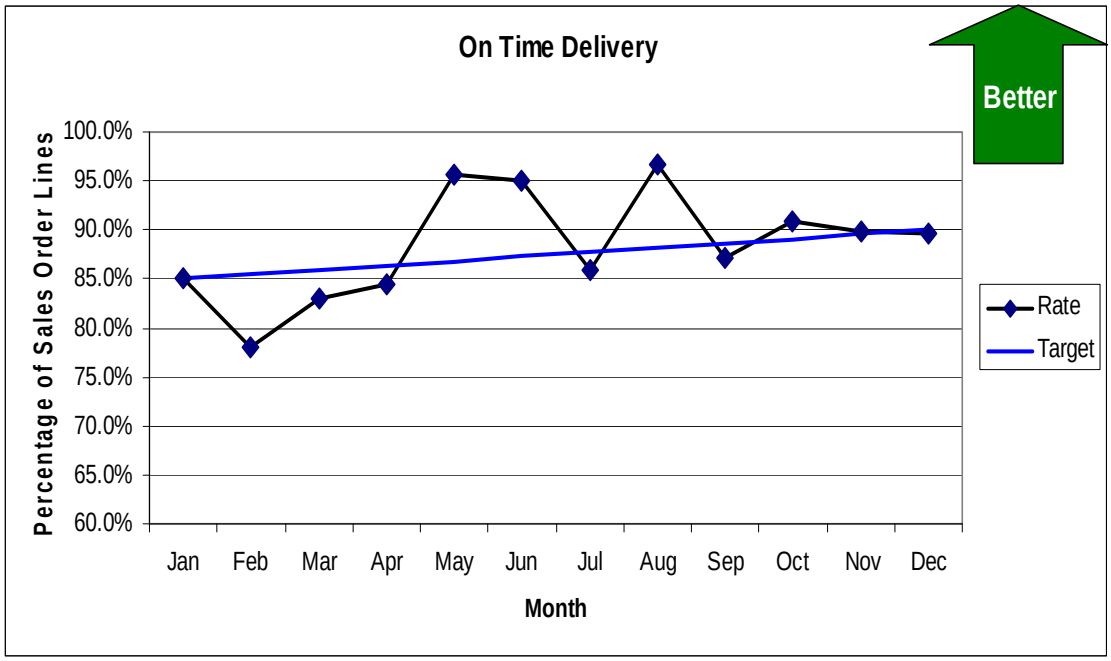
The sections below have a few representative examples.

On Time Delivery Rate
Increase the on-time delivery rate, based on promise date, linearly from 85% in January 2014 to 90% in December 2014

This is a measure of the effectiveness of the fulfillment processes

This is a rate, so we need a numerator and a denominator
Numerator: the number of sales order lines shipped on or before the promise date, *p*
Denominator: the number of sales order lines shipped, *s*
Value: *(p/s) × 100%*
Frequency: calculate the metric for each calendar month

Improvement direction: up, larger values are better



Complaint Corrective Action Closure Time
Reduce the 95% percentile of the complaint closure time linearly from 45 calendar days in January 2014 to 30 calendar days in December 2014

This is a measure of the cycle-time of the Complaint Corrective Action process

The metric is a characteristic of a distribution involving time, so we need to know how to calculate the times and the percentile

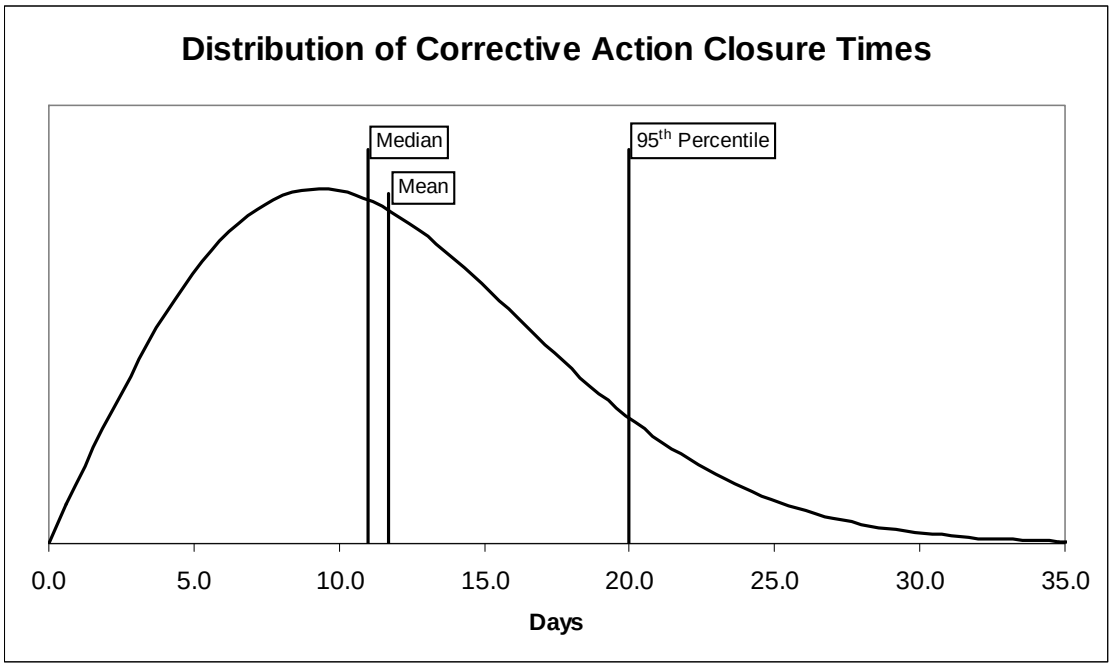
For each complaint corrective action, determine the number of calendar days from the opening date of the CA to the closing date of the CA, the closure time set, *c*

For the closure time set, determine the 95% percentile of the set

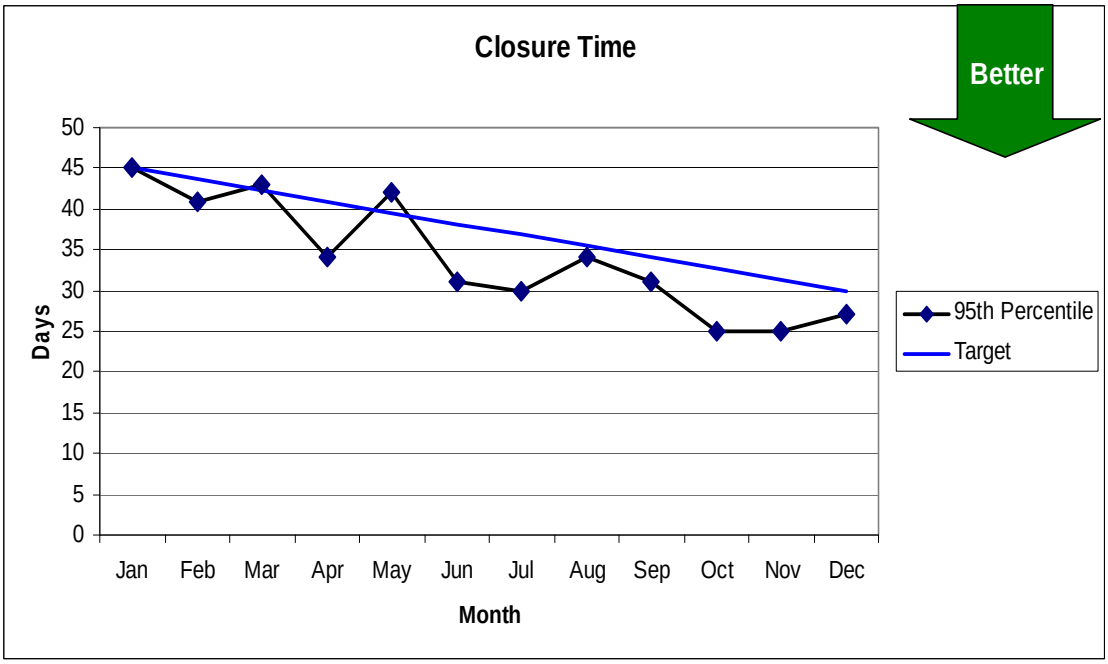
Frequency: calculate the metric for each month

Improvement direction: down, smaller values are better

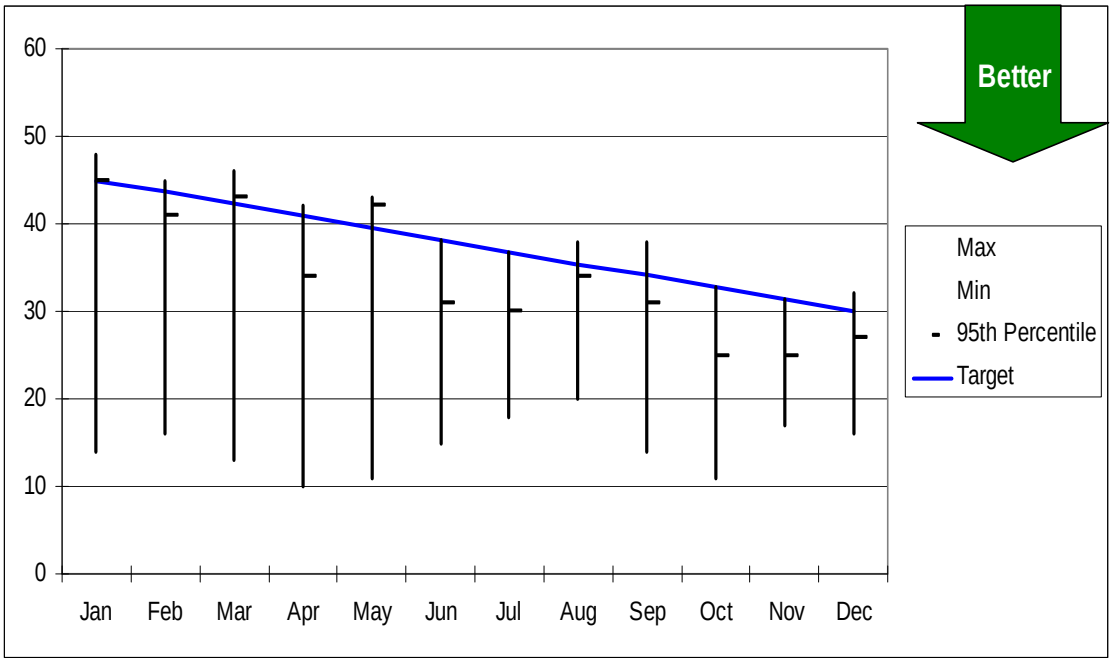
Closure times, especially in corrective actions, have a time distribution that usually has a long tail to the right.



A line graph may be appropriate, as shown below.



A more complete picture, since there is an underlying distribution that can change over time, comes from a series of box plots. However, box plots are difficult in Excel. The Hi-Low-Close graph can provide a good picture of the distribution changes.



Audit nonconformance corrective action closure effort
Reduce the 95% percentile of the audit nonconformance corrective action effort (total hours expended) linearly from 35 hours in January 2014 to 25 hours in December 2014

This is a measure of the efficiency of the Audit Nonconformance Corrective Action process

The metric is a characteristic of a distribution involving hours worked, so we need to know how to calculate the times and the percentile

For each audit nonconformance corrective action, determine the number of hours expended by all employees, *h*

The set should be a 12-month window to ensure sufficient data for analysis.

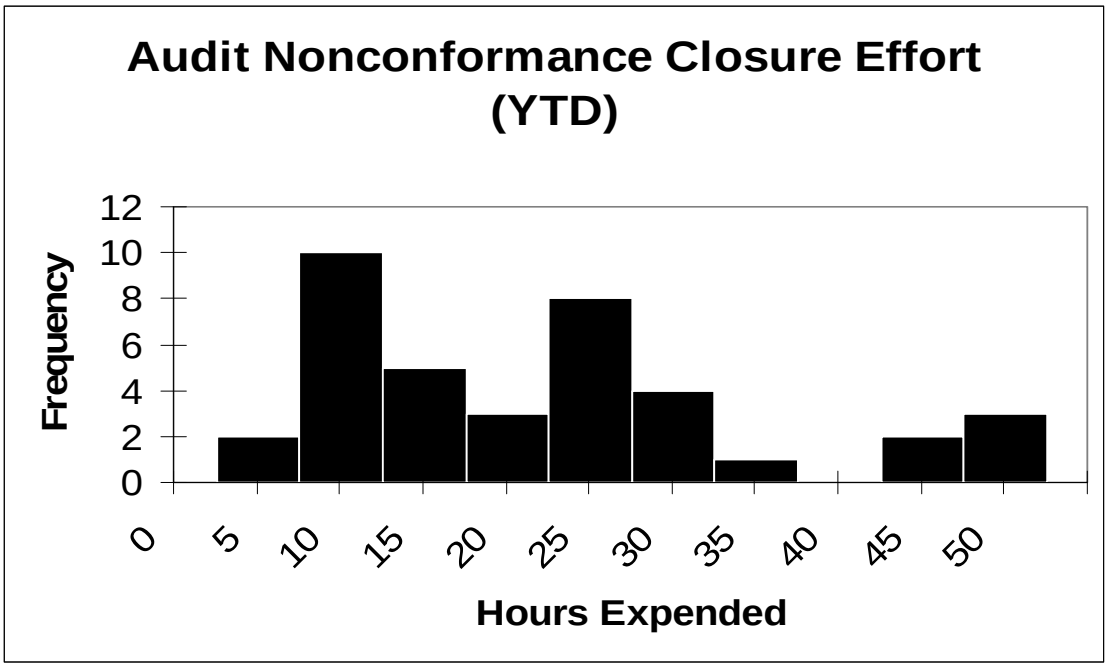
For the closure time set, determine the 95% percentile of the set

Frequency: calculate the metric for each month

Improvement direction: down, smaller values are better

Level of effort, similar to closure times, has a distribution that usually has a long tail to the right.

In this case, as in the closure time, the Hi-Low-Close graph can provide a view over time. In addition, a histogram of the data set could also provide useful information.


Audit Nonconformance Closure Effort (YTD)
Frequency
12
10
8
6
4
2
0
0
5
10
15
20
25
30
35
40
45
50
Hours Expended