

Using and Interpreting Control Charts for Continuous Process Monitoring


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Est 2012



- ✓ ISO 9001
- ✓ ISO 13485
- ✓ ISO 14001
- ✓ ISO 15378
- ✓ IATF 16949
- ✓ ISO/IEC 17025
- ✓ ISO 22442
- ✓ ISO 45001
- ✓ 21 CFR 4
- ✓ 21 CFR Part 210/211
- ✓ 21 CFR Part 820
- ✓ 21 CFR Part 1271
- ✓ EFCI Cosmetics
- ✓ IFS PACsecure
- ✓ AATB Tissue Banking

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Objectives


QUALITY CONTROL



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Requirements for Process Monitoring




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21 CFR 211 Requirements

211.110 Sampling and Testing of In-process Materials and Drug Products
(b) Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications.



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21 CFR 820 Requirements

Sec. 820.250 Statistical Techniques
(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying **valid statistical techniques** required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.




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21 CFR 1271 Requirements

Sec. 1271.220 Processing and process controls
(c) In-process control and testing. You must ensure that specified requirements, consistent with paragraph (a) of this section, for **in-process controls** are met, and that each in-process HCT/P is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received and documented. **Sampling of in-process HCT/Ps must be representative** of the material to be evaluated.




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ISO 9001:2015 Requirements

8.5.1 Control of Production and Service Provision
Controlled conditions shall include, as applicable: c) the implementation of **monitoring** and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.


9.1 Monitoring, Measurement, Analysis and Evaluation
The organization shall determine c) when the **monitoring** and measuring shall be performed.



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The History of Statistical Process Control




Walter A. Shewhart
1891-1967

Dr. W. Edwards Deming
1900-1993

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Why We Use Statistical Process Control



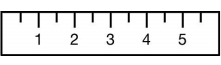
- ✓ Monitor Processes
- ✓ Improve Processes
- ✓ Control Processes
- ✓ Trend Processes

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Types of Control Charts

Variable Data



Attribute Data



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Control Charts

Variables control charts			
Type	Distribution	Sample	Application
\bar{X} and R	Normal	$2 \leq 10$	Measurement subgroups
\bar{X} and s	Normal	> 10	Measurement subgroups

Attributes control charts			
Type	Distribution	Sample	Application
c	Poisson	Constant	Count number of defects per item
u	Poisson	Varies	Count number of defects per item
np	Binomial	Constant	Count of defective items
p	Binomial	Varies	Count of defective items
g	Binomial	Individual	Interval between rare events

Variables or attributes control charts			
Type	Distribution	Sample	Application
\bar{X} and mR	Normal	1	Individual counts or measurements

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How Control Charts Work

μ
 $\pm 1\sigma$ 68.3%
 $\pm 2\sigma$ 95.5%
 $\pm 3\sigma$ 99.7%

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Variation

Common Cause

vs

Special Cause

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Special Cause Variation

- ✓ Equipment, Machines, and Tooling
- ✓ Environment
- ✓ Process
- ✓ Inspection
- ✓ Materials
- ✓ Operator

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Control Chart Interpretation

- Rule 1—One point beyond the 3 σ control limit
- Rule 2—Eight or more points on one side of the centerline without crossing
- Rule 3—Four out of five points in zone B or beyond
- Rule 4—Six points or more in a row steadily increasing or decreasing
- Rule 5—Two out of three points in zone A
- Rule 6—14 points in a row alternating up and down
- Rule 7—Any noticeable/predictable pattern, cycle, or trend

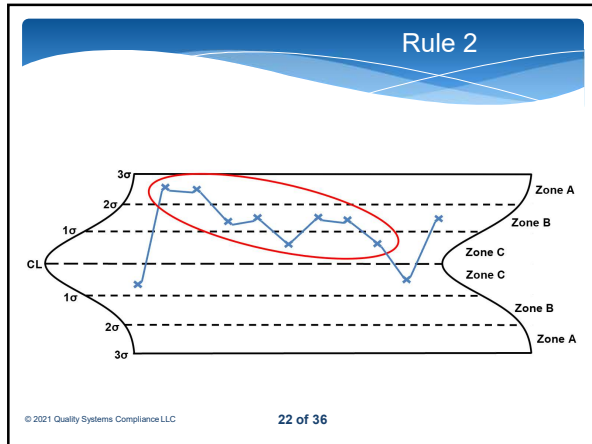
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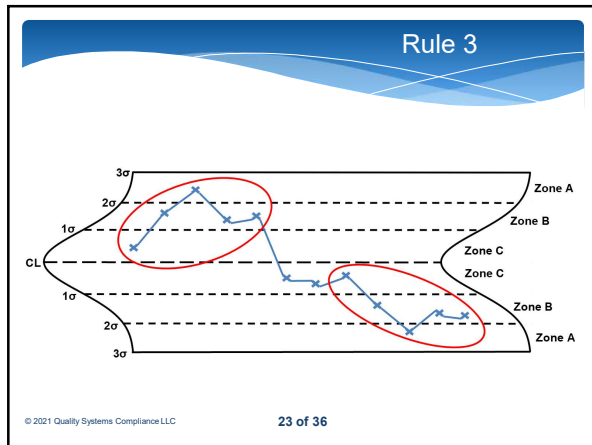
Rule 1

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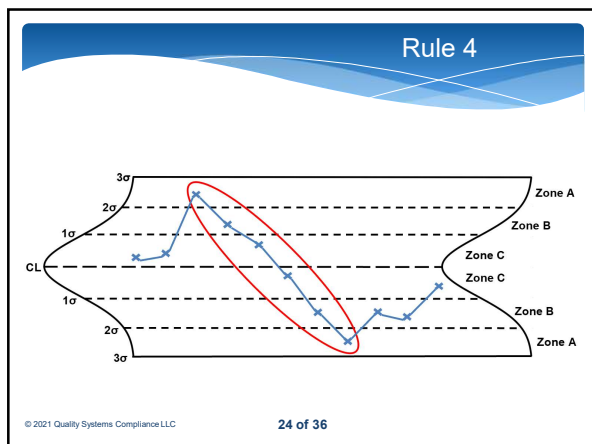
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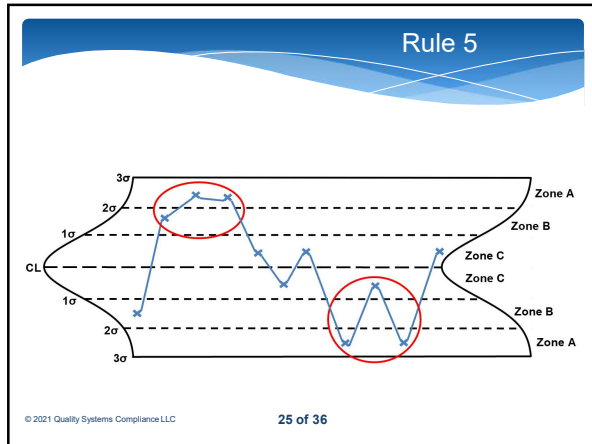
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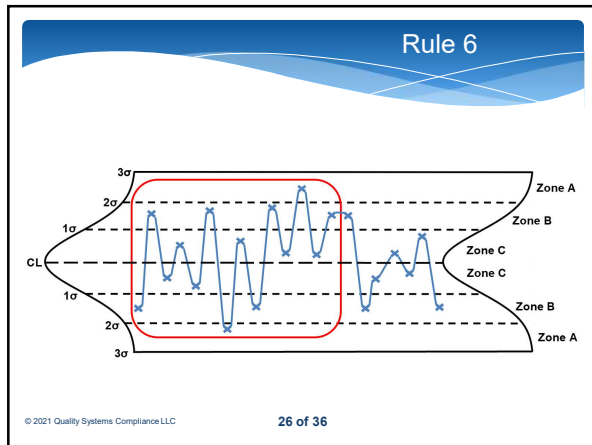
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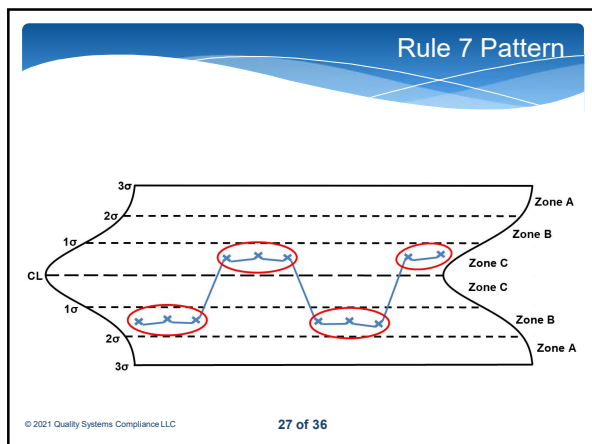
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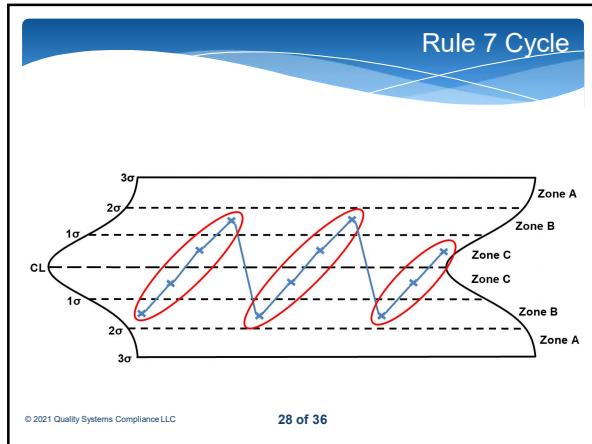
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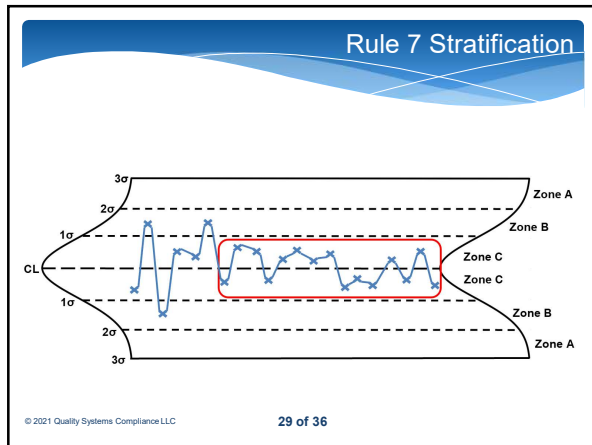
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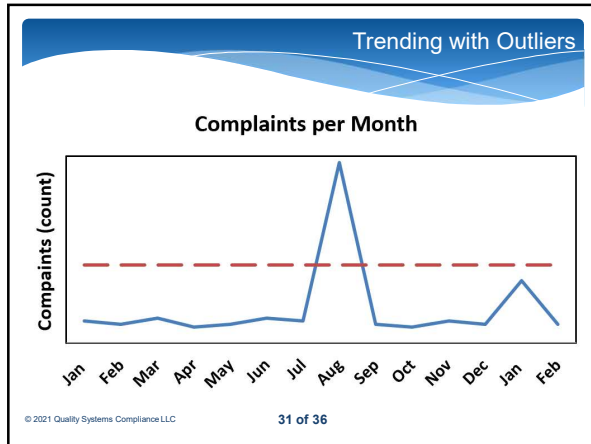
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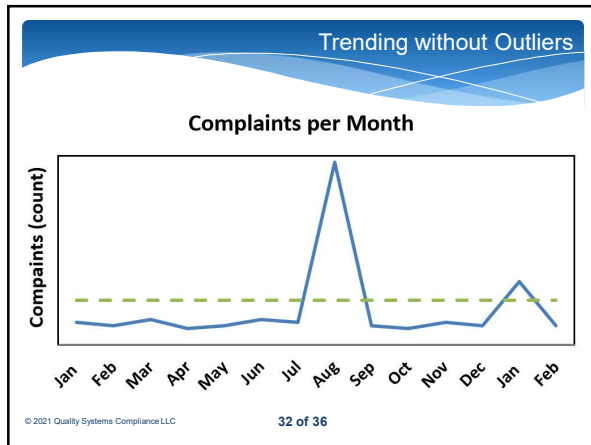
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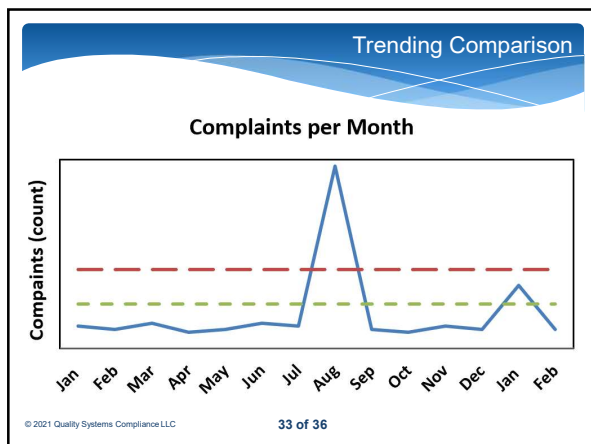
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Summary Comments



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Questions



7 Rules For Properly Interpreting Control Charts
Using Trending As A Tool For Risk-Based Thinking
(meddeviceonline.com or pharmaceuticalonline.com)

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