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# Improve Product Performance Through Annual Review

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# Learning Objectives

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Be able to:

- Perform an Annual Product Review
- Modify it for any industry
- Determine areas for improvement
- Use to measure progress

# Understanding Current Status

- Global impact of the drug industry
- Rising costs
- Health and safety of consumers
- Protect investments
- Maximize profits

# FDA Regulatory Environment

FDA 21 CFR 211.180(e) states that:

“Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes ...”



# FDA Regulatory Environment

Let's see that again....



# FDA Regulatory Environment

“**Written records** required by this part **shall be maintained** so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes ...”



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# Annual Drug Product Review

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- Understand current status
- Identify areas for improvement
- Don't just check the box!



# Annual Drug Product Review

## Overview:

- Production statistics
- Data analysis and compliance
- Non-conformance history
- Rework history
- Complaint analysis
- Change Control

# Scope of the Review

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- Single product or product family
- Size
- Type of container
- Manufacturing site

# Production Statistics

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- Number of lots produced
- Number of lots rejected
- Number of non-conformances
- Number of recalls

# Data Analysis

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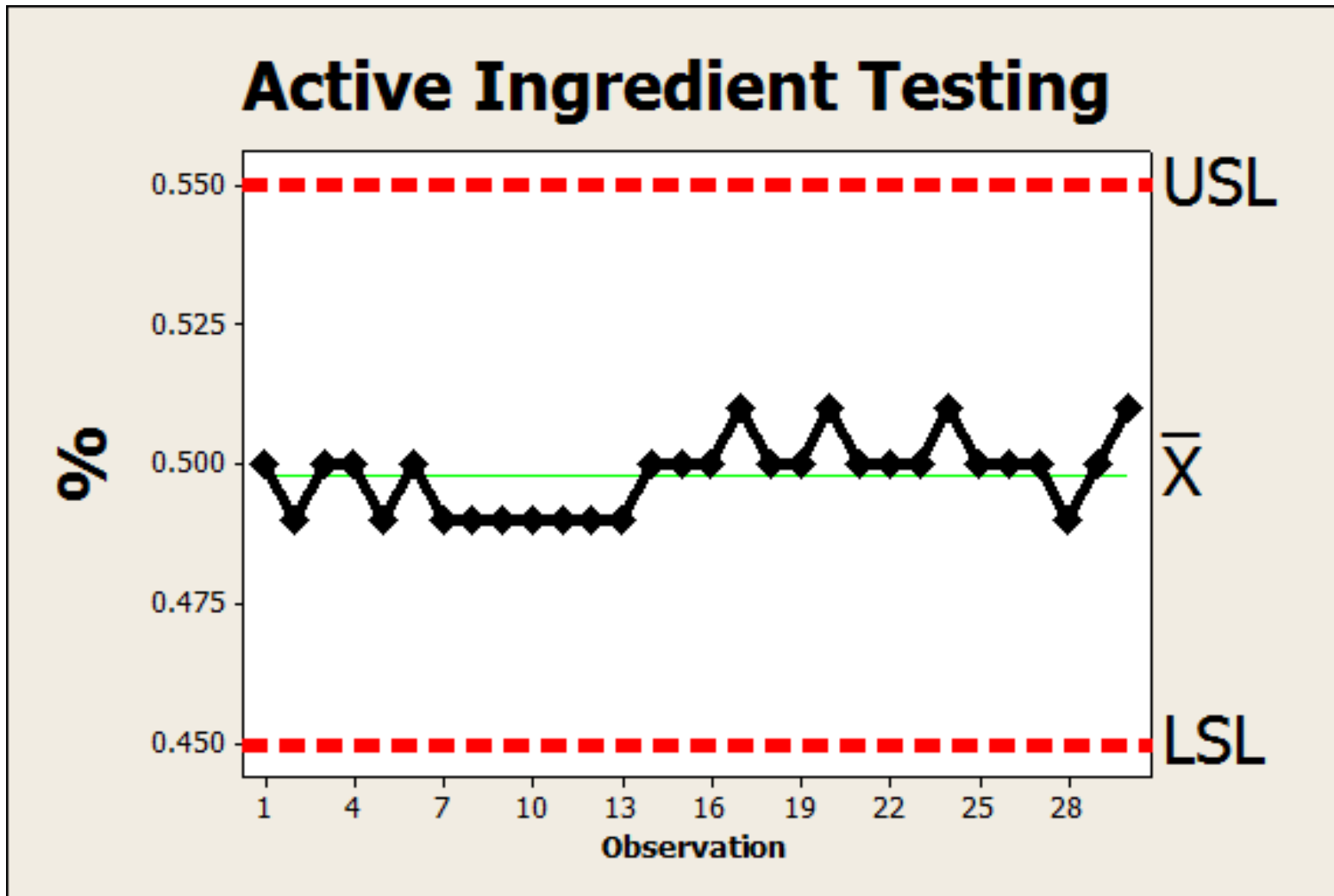
- Finished product
- Raw Materials
- Components
- Process data

# Data Analysis

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- Lab analysis
  - Chemical
  - Physical
  - Microbiological
- In-process testing
  - Weights
  - Torques
  - Anything that is measured

# Time Series Plot

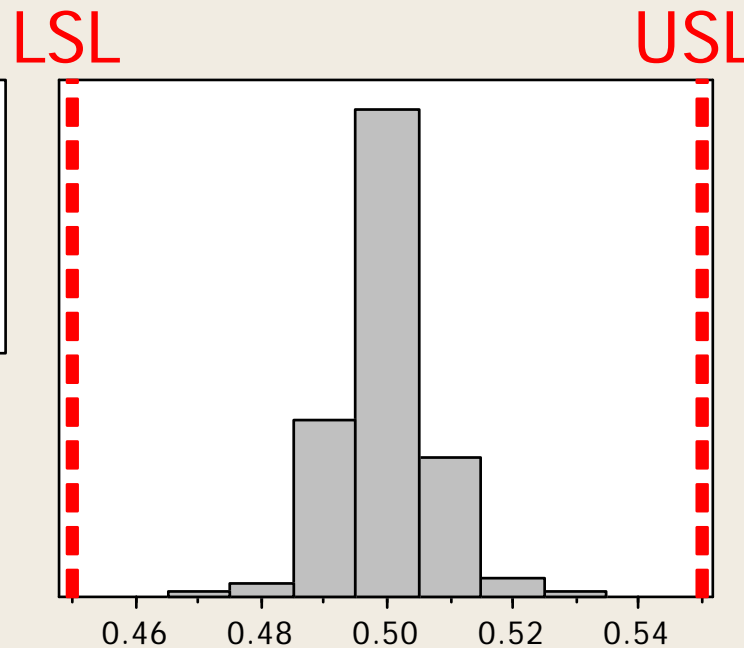




# Process Capability

## Process Capability of Active Ingredient

Process Data	
LSL	0.45
Target	*
USL	0.55
Sample Mean	0.499701
Sample N	134
StDev (Within)	0.00599904
StDev (Overall)	0.00812869



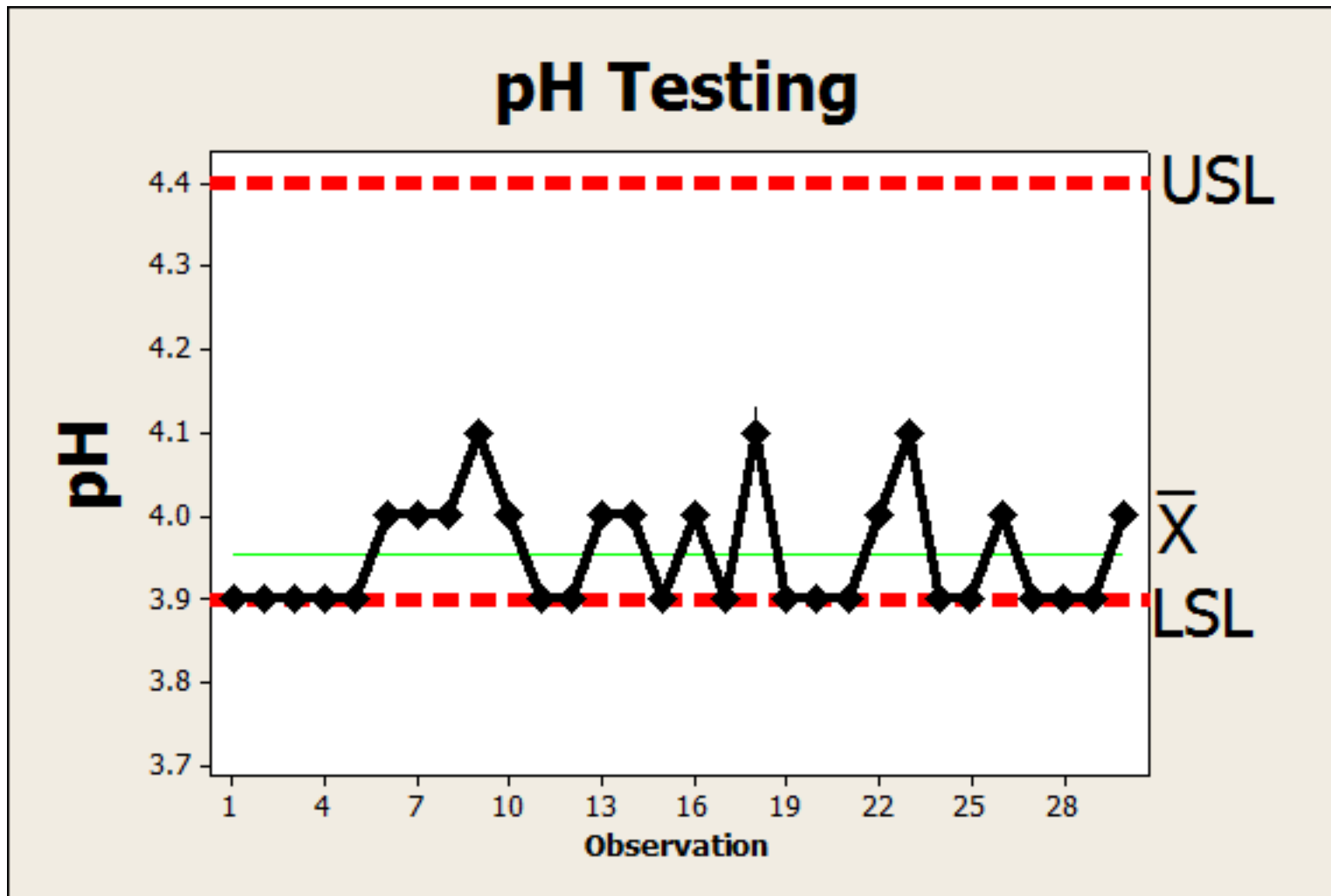
Potential (Within) Capability	
Cp	2.78
CPL	2.76
CPU	2.79
Cpk	2.76
Overall Capability	
Pp	2.05
PPL	2.04
PPU	2.06
Ppk	2.04
Cpm	*

Observed Performance	
% < LSL	0.00
% > USL	0.00
% Total	0.00

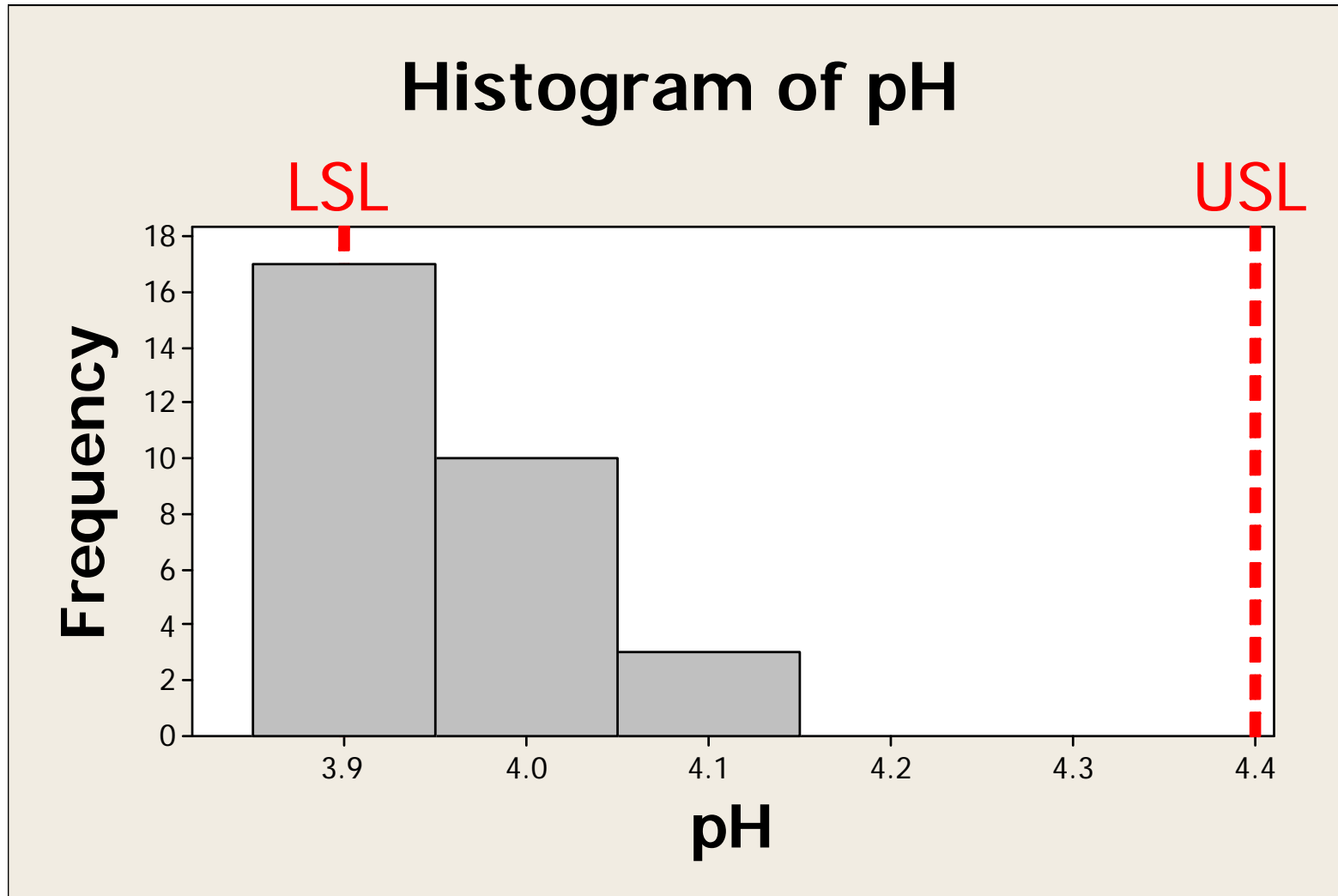
Exp. Within Performance	
% < LSL	0.00
% > USL	0.00
% Total	0.00

Exp. Overall Performance	
% < LSL	0.00
% > USL	0.00
% Total	0.00

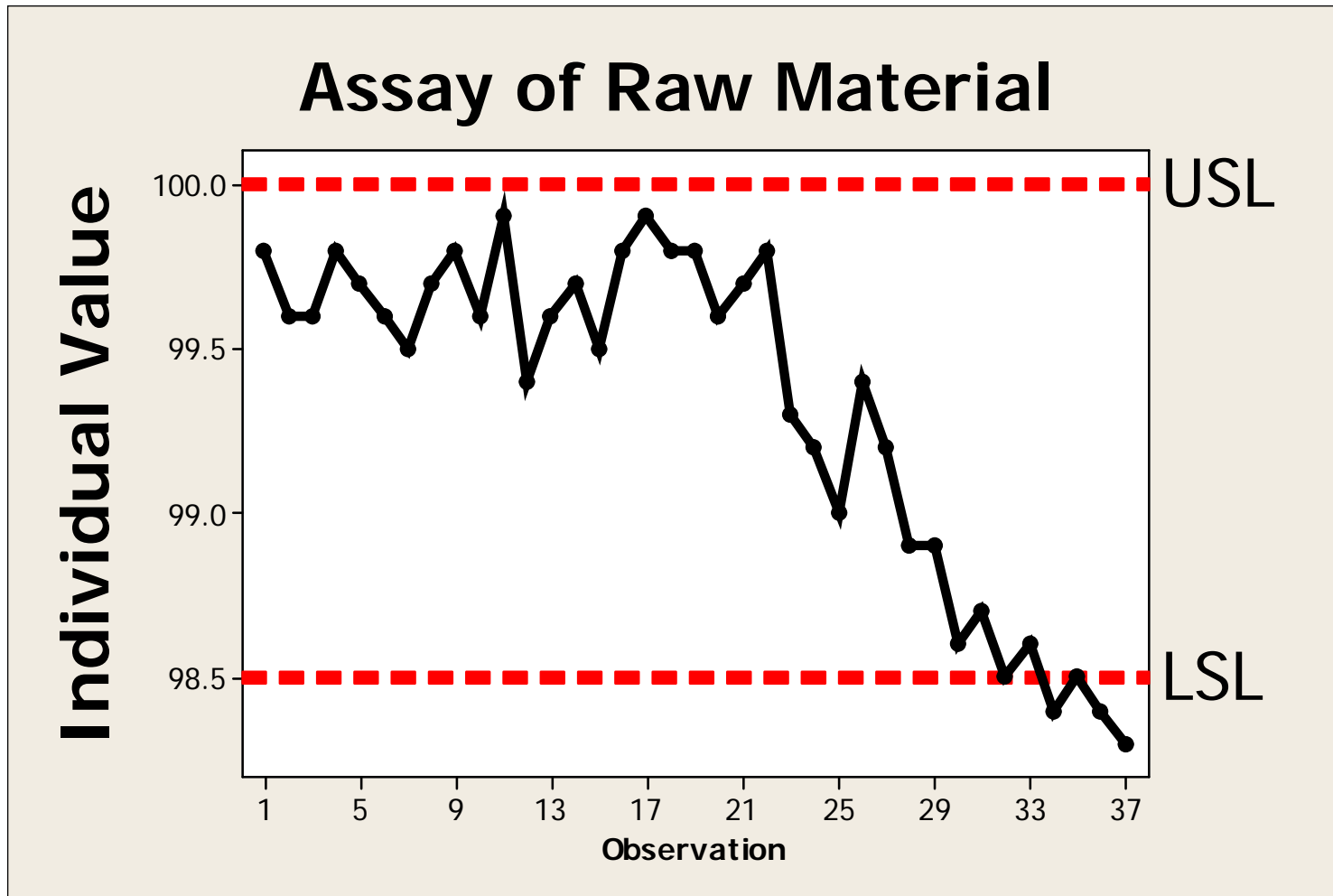
# Time Series Plot



# Histogram



# Raw Material Analysis



# In-process Analysis

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- Weights
- Torques
- Pressures
- Temperatures
- Anything that is measured

# Non-conformance History

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- Out-of-specification incidences
- Repeated incidences
- Root Cause Analysis

# History of Actions Taken

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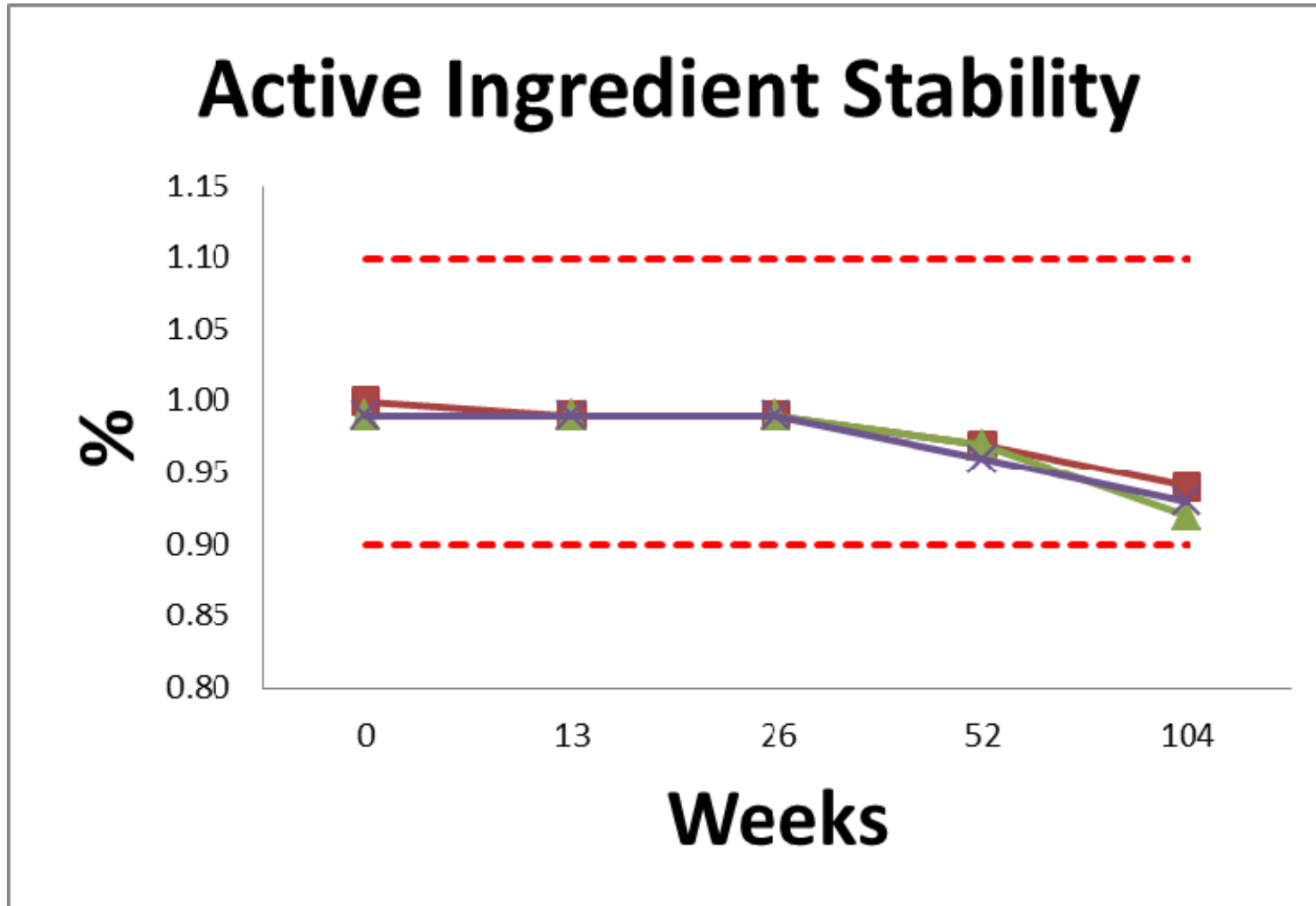
- Corrective Actions
- Preventive Actions
- Responsibility and Timing
- Follow up
- Effectiveness checks
- Tracking

# Rework – The Hidden Factory

- Review rework history
- Trends
- Repeated issues
- Root cause determined
- The Hidden Factory!

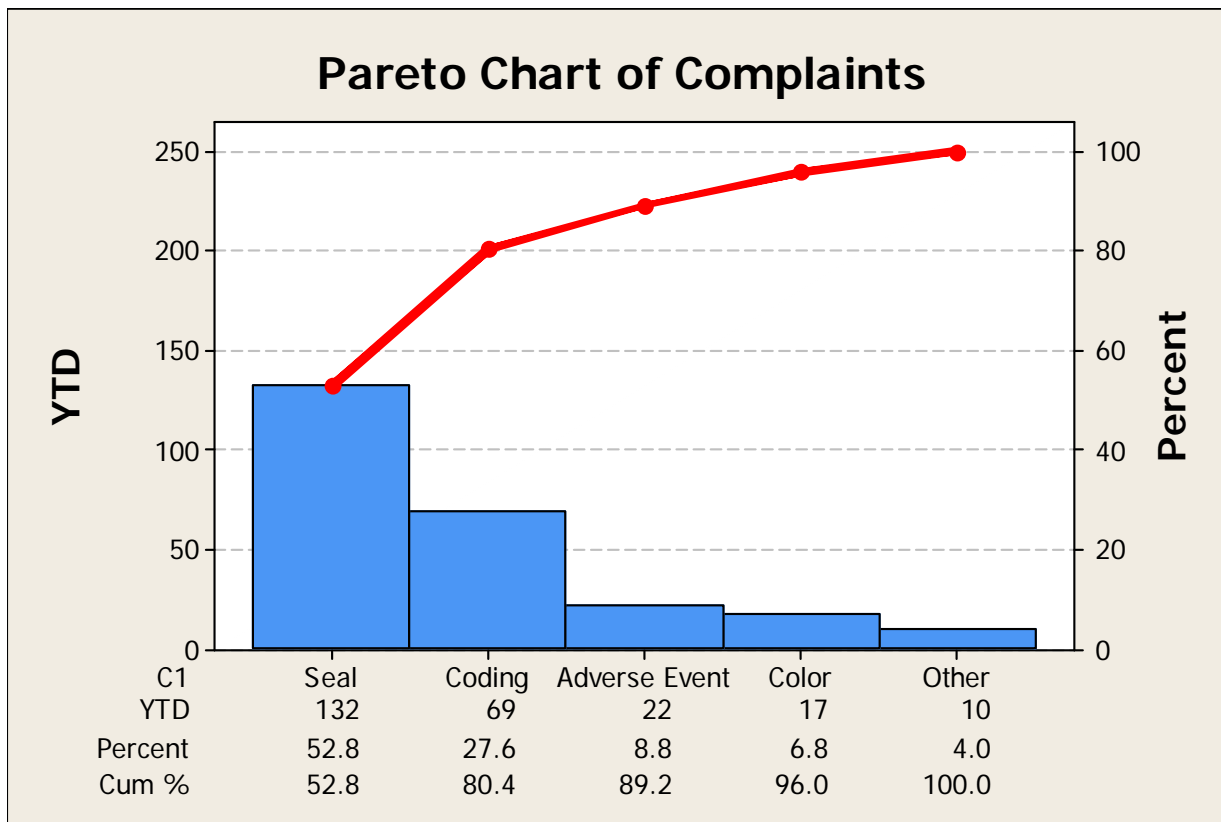


# Stability Data



# Complaint Analysis

- Number by type of complaint
- Pareto chart to determine trends



# Change Control

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- Review the change control history
- Number processed
- Types of changes
- Proactive or reactive?

# Non-drug products

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- Determine critical metrics
- Examples:
  - Reliability data
  - Line Fall-out
  - Mean time to failure
  - Mean time to repair

# Problem Solving



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- “Minor” issue repeats
- Review reveals frequency
- Related customer complaints

= Escalated priority!

# Problem Solving

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- Lotion with lumps
- Emulsion formation problem
- Mix history RPM 
- Raw material viscosity history 
- Root cause = Combination

# Draw Conclusions

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- The state of the product
- The state of the process
- The need for change
- Where to focus resources!

# Next Year...

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- Compare to the previous review
- Has improvement been made?
- Take it all to the next level!



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# QUESTIONS?



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