Understand, Reduce and Control Deviations and Variances

Shannon Winters Goodson, MEM
Process Validation Manager
CSA Soliance
Is the Result a Deviation or a Variance?
What is a Deviation?

• A deviation is a result that varies from the expected “norm” or target value (mean value)

• Error or failure that occurs during the execution of a validation

• 3 Types of Deviations:
  • Simple
  • Non-Critical
  • Critical
3 Types of Deviations

• Simple
  • Documentation or protocol generation errors. Typically typos of “obvious” errors.
  • Usually found prior to execution
  • These generally have no impact on validation and have no real risk to the validation process
3 Types of Deviations

• **Non-Critical**
  - Errors in the protocol or in the execution of the validation which have no impact on the validation, process, system or results
  - Usually found during or after the execution
  - Examples include:
    - Operator not trained to perform the operation
    - Misunderstanding of the operation function or requirements
  - Results may not be out of specification, but are definitely not typical for the process.
3 Types of Deviations

• Critical
  • Errors which have an impact on the validation, these errors are found during or after execution.
  • They directly impact system, process or data integrity
  • Examples of critical exceptions include:
    • Acceptance criterion failure
    • Incorrect settings used during the execution testing
  • Results are out of specification
3 Types of Deviations - Examples

• Simple
  • Protocol generation error (The part number for the pump to be used is incorrect)

• Non-Critical
  • The blow-off air for the part ejection chute is set too high (This is out of specification for operation, but does not affect the final product)

• Critical
  • The curing oven temperature was set too low (The product does not cure correctly, causing it to be too brittle and out of specification)
What is a Variance?

- A variance in results is something that is inherently present in the process.
- It is the deviation that occurs around the mean.
- The result is typically within the specification range, but most likely not on target.
- It can be attributed to certain factors or settings within the process.
What is a Variance - Example

• The cascade flow temperature on the rinse tank is set within the specification range, but is on the high side of that range.

  • The result is that the part temperature coming out of the tank is higher than expected, but still within the acceptable range.

  • The process is within specification and will result in parts within specification, but it is different than the “normal” operation of the process.
Why does it matter if it’s a deviation or a variance?

- It is important to know the difference, so that it is addressed correctly
  - Since a deviation is considered an “abnormal” event, it is generally resolved as a one-off event
  - If the event is actually a variance, then any resolution (for a deviation) may adversely affect the process or create more issues and work
How does a deviation or variance affect my validation?

• A **deviation** may adversely affect the validation in that tests or entire protocols may need to be re-executed
  • The type (simple, non-critical, critical) and the affect on quality will determine the level of testing that may need to be completed

• A **variance**, when documented, tested and known, may not affect the validation at all
  • Evidence of a “normal” occurrence or find that the result is due to certain factors in the process that may happen under normal operating conditions
  • A good understanding of the process and its results will provide the evidence that the end product is good and within specification
Examples of Deviations and Variances

• Glove Manufacturer in the Southern US:
  • The plant manufactures in a non-controlled area – temperature and humidity are not controlled. In the Summer, this is a hot and humid location and in the Winter, it is colder and drier. They are able to make adjustments to their process in order to control the curing of the gloves to be within specification. *These are variances.*

• During a particular cold and dry Winter storm, they were unable to produce gloves within specification. The humidity in the non-controlled production area had dropped to below their allowable range and they could not raise it, so production had to stop for the day. *This was a deviation.*
Is it a Deviation or a Variance?

- It is important to really know the process before starting a validation.
  - Understand the critical process parameters (CPP) and how they affect the critical quality attributes (CQA)
    - Raising the oven temperature may decrease cycle time, but could make the product more brittle
  - Understand how the CPP’s interact with each other.
    - Raising an oven temperature may decrease drying time, but cooling time may need to be adjusted in order to allow proper curing
  - By understanding the CPP’s and the CQA’s and the process capabilities and functions, it is easier to identify Deviations and Variances
Reducing and/or Controlling Deviations and Variances
Can a deviation or variance be controlled?

• The process should be understood enough to be able to mitigate or eliminate any causes of deviation
  • Settings such as air/gas pressure, flow rates for water, steam, etc. that may cause deviations if they are out of specification, need to have controls put in place such as calibrated gauges, automatic controls, monitoring, etc.
  • These controls will help to reduce/eliminate any deviations and could reduce the variation in the process as well.

• The expectation is that deviations may always occur, there should be safeguards in place to mitigate these situations as much as possible.
Is there an acceptable level of variance?

• This will depend on the process
  • Having a good understanding of the CPP’s and CQA’s will help to determine this level
  • Running tests on different CPP settings and evaluating the parts for CQA’s will help determine what is acceptable
  • It is necessary to look at the entire process in order to evaluate this fully.
    • It is entirely possible that a part may be at one end of the acceptable range at an early process, but may not even be able to be processed at a later process. If this is the case, then the variance upstream in the process need to be made tighter.
How can I reduce or control deviations and/or variances?

• Process Characterization
  • CPP/CQA matrix
  • PFMEA

• Design of Experiments

• Statistical Analysis

• Test Runs (PQ or Engineering Tests)
Process Characterization

• CPP/CQA Matrix
  • Map the process by each step
  • Determine the Critical Process Parameter (CPP) at each step
  • Determine the Critical Quality Attribute (CQA) at each step
    • Include any interactions between steps that may not be adjacent, but further downstream

• Use the CPP’s and CQA’s to develop the Risk Assessment Document (PFMEA)
  • Evaluate each process step to determine the possible causes of failure and determine the mitigations that can be put in place in order to reduce or eliminate any deviation and/or variance
Process Mapping – Individual Steps

**IN:**
Component
In

**OUT:**
Component Out with Critical Quality Attributes
Process Mapping – Multiple Step Interactions

Raw Material
- Material Spec
- API: Particle Size
- Polymer
- Moisture Content

Blending
- Powder
- Flowability

Compacting
- Slug
- Friability
- Crush Strength

Compounding
- Material

Pressing
- Solid Tablet
- Scored Tablet
- Thickness
- Compound Yield

Milling
- Milled Powder (Final)
- Milling Yield

Final Product
- Particle Size Distr.
- % Crystallinity
- Potency
- Purity
- [Dissolution]
- Content Uniformity

Tablet (Final)
- Crush Strength
- Dimensions
## CPP/CQA Matrix

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<th>Process Parameters</th>
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[Service Solutions Logo]
### PFMEA – Process Failure Mode Effects Analysis

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<th>New evaluation</th>
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| Risk ID | Cause/Parameter Class | Symptom | Process Parameter/ Function | Potential Failure Mode | Potential Effect(s) of Failure | Probable Cause of Failure | Severity (S) | Occurrence (O) | Detection (D) | FMEA (SOP) | Recommended Actions (Mitigations to be put in place) | Action Taken | Security (S) | Organization (O) | Duration (D) | Follow-up (F) | Result & Root Cause | Mitigation Type | Responsibility & Target Completion Date | Actions Taken |
|---------|-----------------------|---------|-----------------------------|------------------------|-------------------------------|---------------------------|--------------|----------------|-------------|------------|-------------------------------------------------|--------------|---------------|----------------|-------------|-------------|----------------|----------------|----------------|-----------------|---------------|--------------|
| 1       | CP-001                | Processing | Batch Charge into Feeder | Out of Specification/Material Charge | Yield Loss | Inaccurate scale reading | 2 | 4 | 4 | P | Takis should be in periodic Maintenance/Calibration program | Action XX: PM List | 2 | 2 | 3 | 12 | P |
|         |                       |         |                             |                        |                              |                           |              |                |             |            | Operator should verify the post-blend mixture weight added to the feeder (with a reasonable tolerance to the pre-blend subdivision weight), with a secondary sheet recorded in the Batch Record. Or require verification that the system is visually verified as ready (nothing touching the scale, etc.) | Action XX: Batch Record |              |                |              |             |                                 |              |              |                               |              |              |
|         |                       |         |                             |                        |                              |                           |              |                |             |            | Batch Records shall be followed by QA, per [QA SOP] | Action XX: QA SOP - Batch Record Review SOP |              |                |              |             |                                 |              |              |                               |              |              |
|         |                       |         |                             |                        |                              |                           |              |                |             |            | Daily Balance Sheet shall be logged per [SOP] | Action XX: Logging step in SOP |              |                |              |             |                                 |              |              |                               |              |              |
| 2       | CP-001                | Processing | Batch Charge into Feeder | Out of Specification/Material Charge | Yield Loss | Operator spills mixture during feeding | 2 | 5 | 3 | D | Operator shall record change leading completion, with a secondary sheet recorded in the Batch Record. Material are to be new into Feeder via system and form/mix appropriate for the process, as per Equipment SOP/Batch | Action XX: Batch Record - checkbox for success, spot for contamination/loss issues | 2 | 2 | 3 | 12 | P |
|         |                       |         |                             |                        |                              |                           |              |                |             |            | Material are to be new into Feeder via system and form/mix appropriate for the process, as per Equipment SOP/Batch | Action XX: Develop Equipment SOP |              |                |              |             |                                 |              |              |                               |              |              |
|         |                       |         |                             |                        |                              |                           |              |                |             |            | Equipment SOP shall require supervisor notification in case of material loss | Action XX: Develop Equipment SOP |              |                |              |             |                                 |              |              |                               |              |              |
|         |                       |         |                             |                        |                              |                           |              |                |             |            | Batch Records shall be | Action XX: QA SOP |              |                |              |             |                                 |              |              |                               |              |              |
Design of Experiments (DOE)

• First Stage is generally a determination of the Critical Process Parameters and their effect on the product (Temp, Pressure, time, etc.)

• Use Design of Experiments (DoE) to establish the ranges of the CPP’s
  • Use incremental changes of one parameter to establish the effect and determine the ideal settings. (If a range for temperature is 100-200°C, then increase by 20°C)
  • Take a small sample set (less than 20) from each run in order to take measurements and verify Quality Attributes of product
  • Compare the final product samples from each of the runs to the product specifications.
  • Calculate the mean and standard deviation for each sample set against the product specifications
Statistical Analysis

- Averages, medians, mode and standard deviation
  - Average = Total/Number of Samples
  - Median = The Middle number in a list of sorted numbers
  - Mode = The number that appears most often in a set of numbers
  - Standard Deviation (SD) = \( \left(\frac{\sum(x_i-x_{\text{bar}})^2}{(n-1)}\right)^{0.5} \)
    - 1SD = 68% of Data
    - 2SD = 95% of Data
    - 3SD = 99.7% of Data
    - 4SD = 99.9% of Data
    - 5SD = 99.98% of Data
    - 6SD = 99.9997% of Data
Statistical Analysis

• Cpk or Process Capability
  - Cpk =
    Minimum of $= \frac{\text{Upper Spec} - \text{Mean}}{3s} \quad ; \quad \frac{\text{Mean} - \text{Lower Spec}}{3s}$

$s = \text{standard deviation}$

Cpk is an index which measures how close a process is running to its specification limits, relative to the natural variability of the process

Target for Cpk is:
  1.33 (or 4 sigma) for existing processes
  1.50 for new processes
  1.67 for new safety critical processes
  2.00 = 6 sigma
Why is it important to understand the process BEFORE starting the validation?

• A good understanding of the process is critical to being able to execute a successful validation

• Establishing the expected values of the results of the process, reduces the guess-work of whether a value is a variation or a deviation

• Through an understanding of the process and the Critical Process Parameters and Critical Quality Attributes, it is possible to eliminate some validation testing (OQ & PQ) in order to focus on testing the CPPs/CQA’s only.
Interactive Exercise