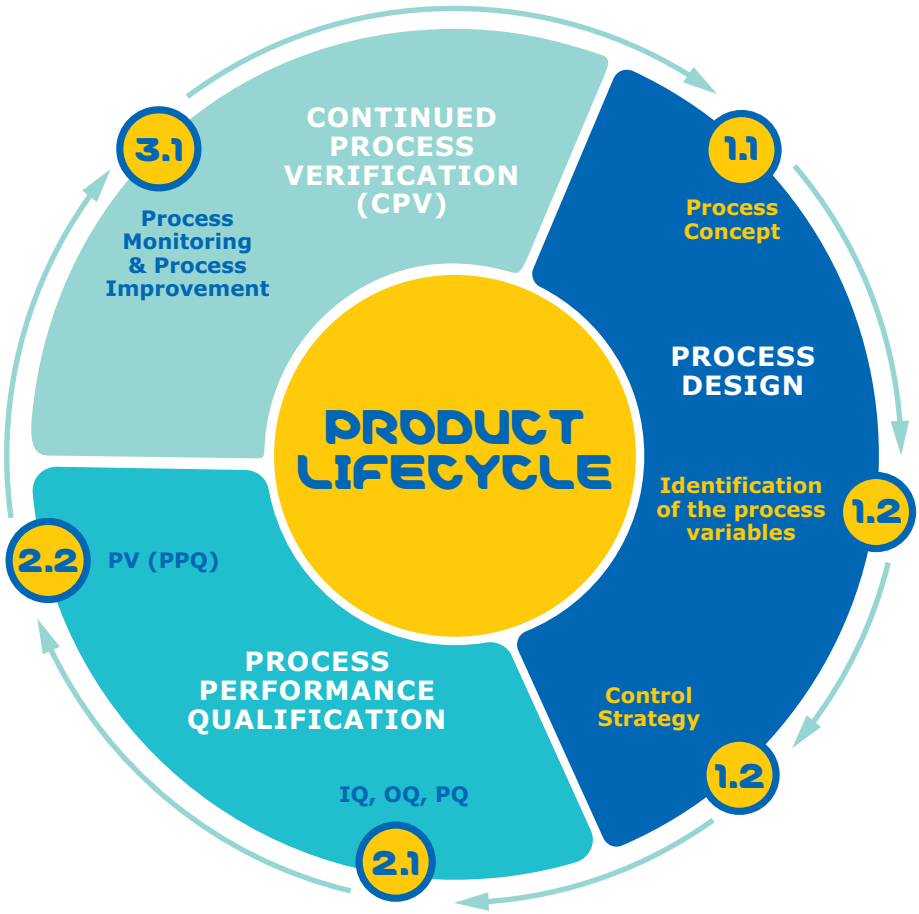
Millipore®
Preparation, Separation,
Filtration & Monitoring Products

CPV E-BOOK

IMPLEMENTING

CONTINUED PROCESS VERIFICATION

with Bio4C™ ProcessPad



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Background

The Food and Drug Administration (FDA) guidance on continued process verification and the EU GMP Annex 15 requirements for ongoing process verification direct pharmaceutical and biopharmaceutical manufacturers to ensure that their processes remain in a continual state of control (a validated state) during the lifecycle of the product so that the strength, quality, and purity of the final drug product is maintained. Both regulatory agencies direct manufacturers to develop sustained programs which collect and analyze product and process data to evaluate the state of control and to identify product or process problems or opportunities to implement improvements.

A product's lifecycle normally consists of 3 phases: process design, process performance qualification, and the last and lengthiest, continued process verification (CPV) which carries on throughout the lifespan of the product (Figure 1.)

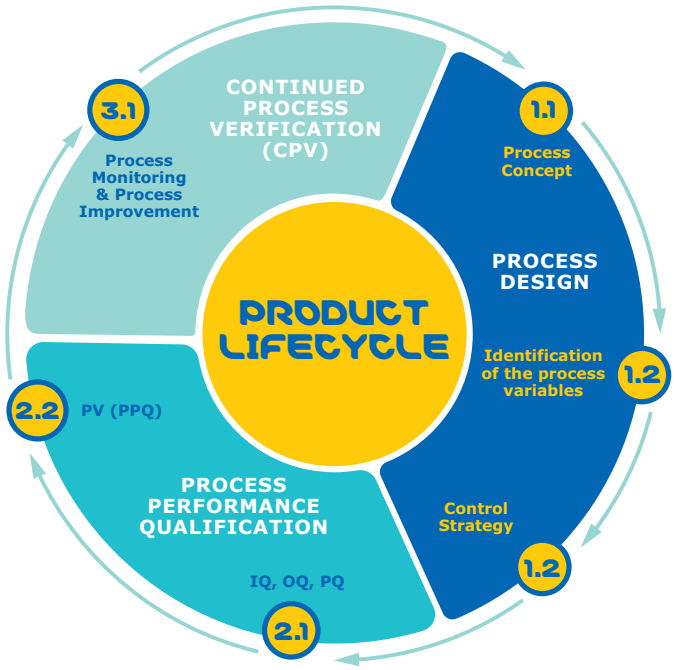


Figure 1. Product Lifecycle

Until recently biopharmaceutical manufacturers focused predominantly on the process design and process performance qualification phases of the product lifecycle; given recent FDA and EMA guidance to institute ongoing programs to collect and analyze product and process data, the industry is now giving equal attention to CPV. CPV has become a part of the observations in recent warning letters of regulators either due to lack of complete understanding of the concept or lack of right tools to perform CPV in an efficient way. Below are some excerpts from the FDA warning letters.

In pharmaceutical and biopharmaceutical manufacturing, the amount of process and analytical data per batch is very high. If a structured procedure is not followed, manually collecting the data and trending it statistically is time-consuming and error prone. Among many tasks, CPV requires collecting process parameter data, trending it against statistical control limits, and calculating process capability (Cpk and Ppk) at defined intervals or after every few batches. Since a structured CPV program is now a regulatory expectation for process manufacturing and quality operations, the industry seeks an automated software solution built specifically for ongoing process verification.

Bio4C™ ProcessPad is a data visualization, analytics, and process monitoring platform that enables bioprocess lifecycle management, reporting, investigations, and continued process verification. It allows biopharmaceutical scientist to collect and manage data from paper-based records, spreadsheets, batch record data, quality control data, external databases, data historians, and streaming machine data in a single software environment. Bio4C™ ProcessPad provides data visualizations and analytical tools for straight forward statistical trending of data control charts, correlation charts, box plots, etc. It also offers easy reporting including campaign reports, process summary reports, Annual Product Reviews (APRs) and Annual Product Quality Review (APQR). Along with offline monitoring of data, the Bio4C™ ProcessPad-RT collects, aggregates, and provides direct web-browser access to real-time streaming data from processing equipment such as bioreactors, chromatography systems, buffer systems, etc.

Process Controls

Your firm does not have an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality. See FDA's guidance document, Process Validation: General Principles and Practices, for general principles and approaches that FDA considers appropriate elements of process validation, at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf

(D) You have not conducted Stage III Continuous Process Verification (CPV) to ensure that commercial products remain in a state of control. The requirement to implement continuous process verification was introduced in SOP No. [redacted]. You have only conducted Stage III Continuous Process Verification on [redacted] (b)(4). The rationale for selecting this product for CPV is not documented and you do not have any documented plans to conduct the CPV activities on other products commercially distributed in the U.S. market.

process validation and positioning of cpv

From the process design stage through commercial production, process validation collects and evaluates data and establishes scientific evidence that a process is capable of consistently delivering quality product.

Process validation involves a series of activities taking place over the lifecycle of the product and process. Its activities can be divided into three stages:

1. **Process Design:** The commercial manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities.
2. **Process Qualification:** During this stage, the process design is evaluated to determine if the process is capable of reproducible commercial manufacturing.
3. **Continued Process Verification:** Ongoing assurance is gained during routine production that the process remains in a state of control.

In this eBook we will outline a strategy and all the associated components required to establish a compliant and efficient CPV program.

Successful process design and process qualification determine that the process can reproducibly produce a commercial molecule. Continued process verification ensures that the process remains in a state of control and is steadily producing a medicine of desired quality. Unlike process validation's first two stages which have a distinct endpoint, CPV is sustained for the life of a drug molecule and requires a comprehensive strategy. Following are the key components required to establish a CPV program:

1. Parameter classification and statistical treatment of data
2. Determining process capability (Cpk) and process performance (Ppk)
3. Parameter monitoring
4. Out-of-trend detection rules
5. Documentation and reporting

Parameter Classification and Statistical Treatment of Data

Parameter Classification

Process Characterization, Process Validation or *In-process Control* process description documents define parameter classifications and set initial action or specification limits. Table 1 summarizes the parameter definitions and their role in process monitoring. All the Critical Process Parameters (CPP) and Key Process Parameters (KPP) mentioned in the process description documents should be monitored in the program. Monitored parameters (MP) are optional and ought to be selected on a case-by-case basis based upon relevant subject matter expert prior manufacturing experience and process development knowledge. A risk analysis can also be performed to from each parameter type.

In the next step, limits are defined and applied to each parameter type.

Table 2 describes all the limits which need to be considered during process monitoring.

Table 1. Parameter Types

Parameter Type	Abbreviation	Description	Routine Monitoring
Critical Process Parameter	CPP	A performance or input parameter that directly impacts product identity, purity, quality, or safety.	Must
Key Process Parameter	KPP	A performance or input parameter that directly impacts CPPs or is used to measure the consistency of the process step.	Must
Monitored Parameter	MP	A performance or input parameter that may or may not impact KPPs and is used to measure the consistency of the process step or routinely trended for troubleshooting purposes.	Not all, case by case basis

Table 2. Limit Types and Applications

List Name	Abbreviation	Description	Limits Source	Applicable to Parameter Type
Specification Limits	USL, LSL	These limits are defined based on process characterization limits. Any excursion from these limits will cause out of specification and batch rejection.	Process Characterization, Process Development	CPP
Action Limits	UAL, LAL	These limits are process validation ranges. Any excursion from these limits will cause major process deviation or discrepancy.	Process Validation	CPP, KPP
Alert Limits or Statistical Control Limits	UCL, LCL	These are monitoring ranges derived from historical runs for out of trend detection and measurement of process consistency.	Statistical: Process History >15 commercial batches	CPP, KPP, MP
Target	CL	The target (or centerline) is derived again from historical runs as a measure to keep the process consistent and proactively alert if process is deviating from set target.	Statistical: Process History >15 commercial batches	CPP, KPP, MP

Note: CL=centerline, UCL=upper control limit, LCL=lower control limit, SD = standard deviation

Specification limits and action limits are defined during process design and qualification and the first 15 to 30 batches can be trended against these limits. Alert limits (or statistical control limits) should then be defined based on these historical/initial 15 to 30 batches.

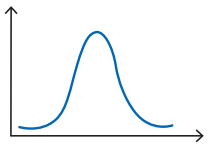
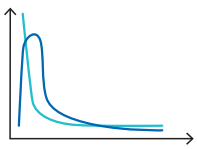
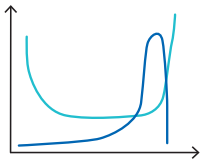
Statistical Treatment of Data

Once the parameter criticality for the desired product quality is determined and parameters classified accordingly, the next step is to perform statistical treatments on the data to determine statistical control limits for the desired performance parameter.

Determining the Distribution of Data for Each Process Parameter

Different types of data distributions and statistical treatment for control limits evaluation for each distribution type.

Table 3. Data Distribution and Statistical Treatments

Distribution	Sample Graph	Description and Examples	Typical Limits Applied
Normal		Most of the process parameters will follow this distribution of a normal/Gaussian bell shaped curve.	CL Average UCL Average + 3 SD LCL Average – 3 SD
Non-normal (Beta or Gamma)	 	Some parameters will not follow a normal distribution pattern and follow a skewed distribution. For example most of the data related to process impurities will be skewed towards the lower bound (approaching a value of 0). Some parameters like cell viabilities would be skewed toward the upper bound (approaching a value of 100%).	CL Median UCL 99.865th Percentile LCL 0.135th Percentile

Setting Up the Control Limits.

How data is distributed determines the procedure for setting up in-process control limits for the continued process verification program (Figure 2).

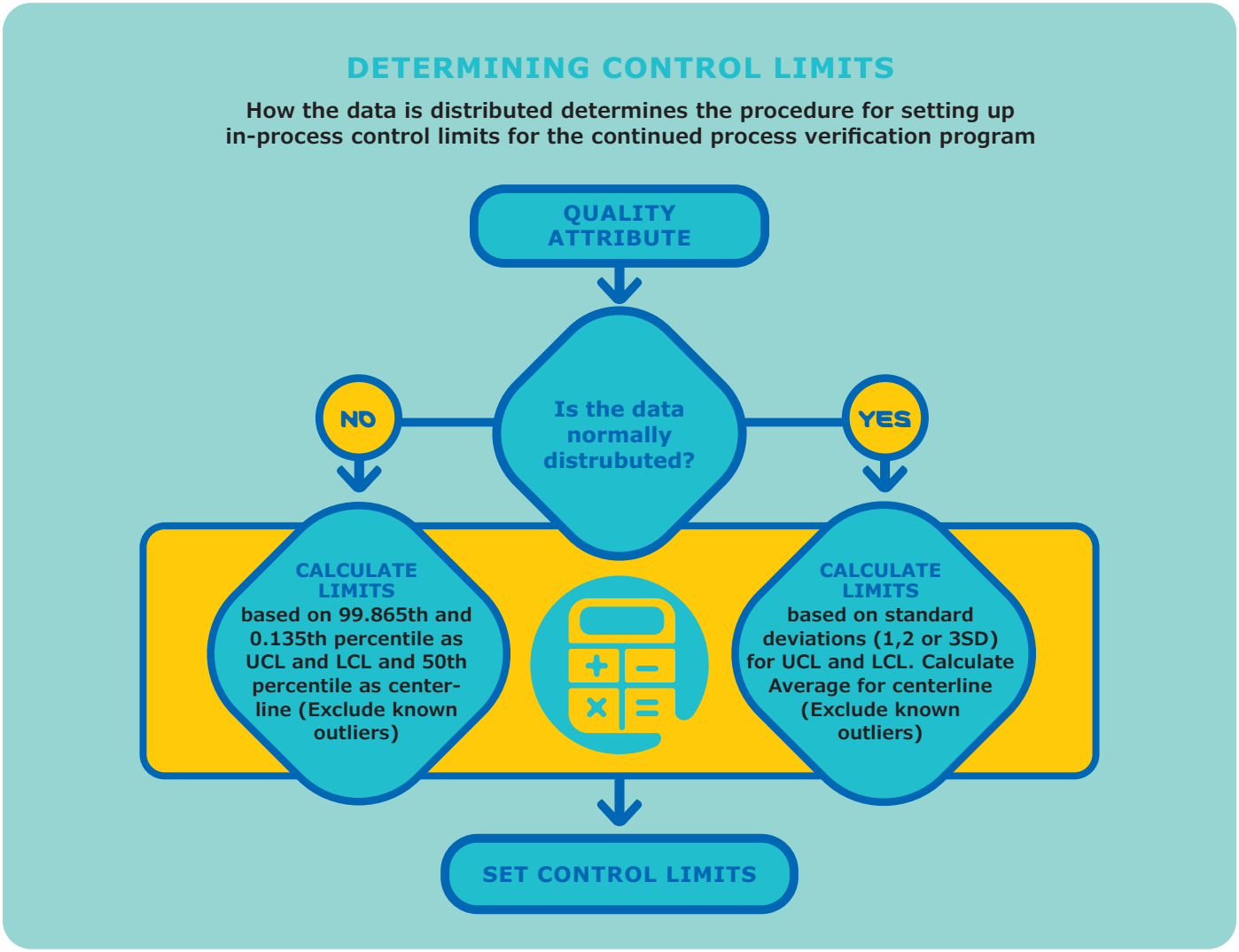


Figure 2. Determining Control Limits

Rules for Excluding or Including Data Points

The batches used for control limit estimation should represent only the inherent process variability (common cause variations). To represent the true processes against which future process results can be compared, all batches with special causes or assignable root-cause deviations (for example, arising due to process changes, equipment failures, mechanical faults, operator errors etc.) should be excluded from limit calculations. When a process change is applied, the control limit calculations should restart for monitoring parameters for the process steps affected with change (and all impacted steps downstream of the affected process step) starting from batche where the process change is applicable.

Once the control limits for all the CPPs and KPPs (parameters being monitored) are defined, it should be documented in an *In-process Control and Monitoring* (IPCM) document.

Setting Up Statistical Process Control (SPC)

Statistical process control (SPC) is an important element of CPV and a process control chart (Figure 3.) plays the most important role in SPC and any process monitoring program. A successful CPV system should not only create SPC charts from validated data, it should also store, display, and evaluate the control chart statistics based on historical limit changes. Hence, an efficient CPV system should always have the capability to capture not only historical data, but also the contextual knowledge (meta data) of historical changes in control limits.

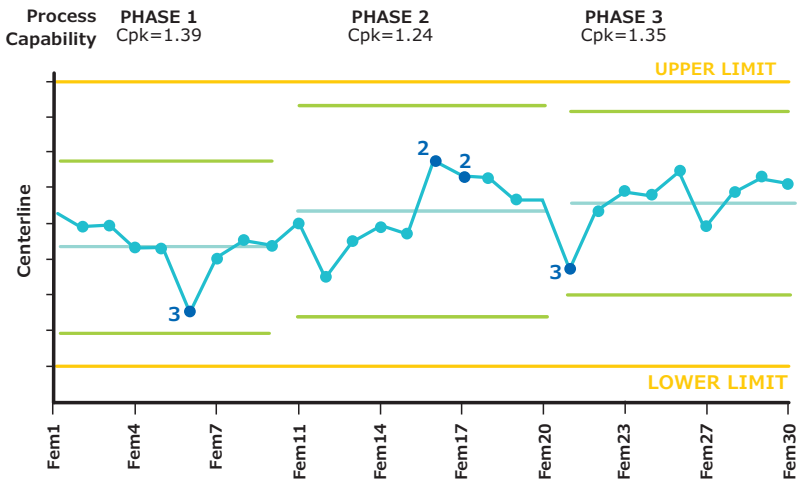


Figure 3. Process Control

Determining Process Capability (Cpk) and Process Performance (Ppk)

A manufacturing process is a unique combination of its manufacturing environment comprised of machines, methods, and people engaged in the production process. Process capability indices provide a quantitative way to determine the performance and future capability of the process within the desired quality boundary for the given manufacturing environment.

Process capability indices have been used in manufacturing to provide quantitative measures on process potential and performance. The output of a process can be a product characteristic or a process output parameter. Process capability indices (Cp, Cpk,) provide a common metric to evaluate and predict the performance of processes and summarize process performance relative to a set of specifications (i.e. quality boundary).

Periodic capability studies should be conducted to predict the overall ability of a continuous distribution process to make products within the required specifications.

Estimating Process Capability for Normally Distributed Data

Process capability (Ppk, Cpk) for a normally distributed monitoring process parameter will be calculated using the following:

$$\text{Ppk} = min\{\frac{(USL-Avg)}{3\sigma}, \frac{(Avg-LSL)}{3\sigma}\},$$

$$\text{Cpk} = min\{\frac{(USL-Avg)}{3\sigma_{MR}}, \frac{(Avg-LSL)}{3\sigma_{MR}}\}$$

Where

USL = Upper Specification Limit (for CPP) or Upper Action Limit (for KPP)

LSL = Lower Specification Limit (for CPP) or Upper Action Limit (for KPP)

Avg = Average or mean of the population under analysis

σ = Standard deviation of the population under analysis

σ_{MR} = Moving Range Standard Deviation

Estimating Process Capability for Non-Normally Distributed Data

Since the average and standard deviations will not represent the non-normally distributed data correctly, process capability (Cpk) cannot be estimated for non-normal data. Instead Process performance (Ppk) will be evaluated based on all of data points in terms of percentile ranges. For a non-normally distributed monitoring process parameter, Ppk will be calculated using the following:

$$\text{Ppk} = min\{\frac{(USL-X_{0.50})}{X_{0.99865}-X_{0.50}}, \frac{(X_{0.50}-LSL)}{X_{0.50}-X_{0.00135}}\}$$

Where

USL = Upper Specification Limit (for CPP) or Upper Action Limit (for KPP)

LSL = Lower Specification Limit (for CPP) or Upper Action Limit (for KPP)

$X_{0.50}$ = Median of the population under analysis

$X_{0.99865}$ = 99.865th Percentile of the population under analysis

$X_{0.00135}$ = 0.135th Percentile of the population under analysis

Parameter monitoring

During process monitoring, a performance parameter under the monitoring program will undergo different monitoring modes (or phases) depending upon the number of data points and accumulated history of the parameter being monitored.

Monitoring phases

Different monitoring phases (Figure 4) are explained in the following diagram.

Preliminary Process Monitoring Phase

The Preliminary Process Monitoring (PPM) phase is primarily a data collection or accumulation phase for obtaining enough historical information to make reasonable assumptions on inherent variability (common cause variation) of the parameter and estimate a statistical control limit with reasonable confidence. The PPM phase should run for a minimum of 15 data points. During this phase no statistical control limits will be applied to any parameter types.

Statistical Process Control (SPC) Phase

Once the basic history of a parameter (capturing common cause variability) is accumulated, control limits will be established using statistical methods and procedures described in earlier sections.
All parameter data received after the PPM phase will be trended against these newly established control limits.

Resetting or Revising Control Limits

Control limits should be periodically re-evaluated, revised, or reset as appropriate based on the following:

Enough Batch History

Alert limits should be periodically re-evaluated after every 25-30 batches after entering the SPC phase. This will prompt tightening or widening of limits based on further accumulated process knowledge. The batches used for limit evaluation should be free from any special cause variation.

Process Changes

If changes to processes are introduced after entering the SPC monitoring phase, the alert limits should be reset, and all parameters affected downstream of where the change was introduced should enter the PPM phase to re-gather history for new process conditions until it enters SPC phase again.

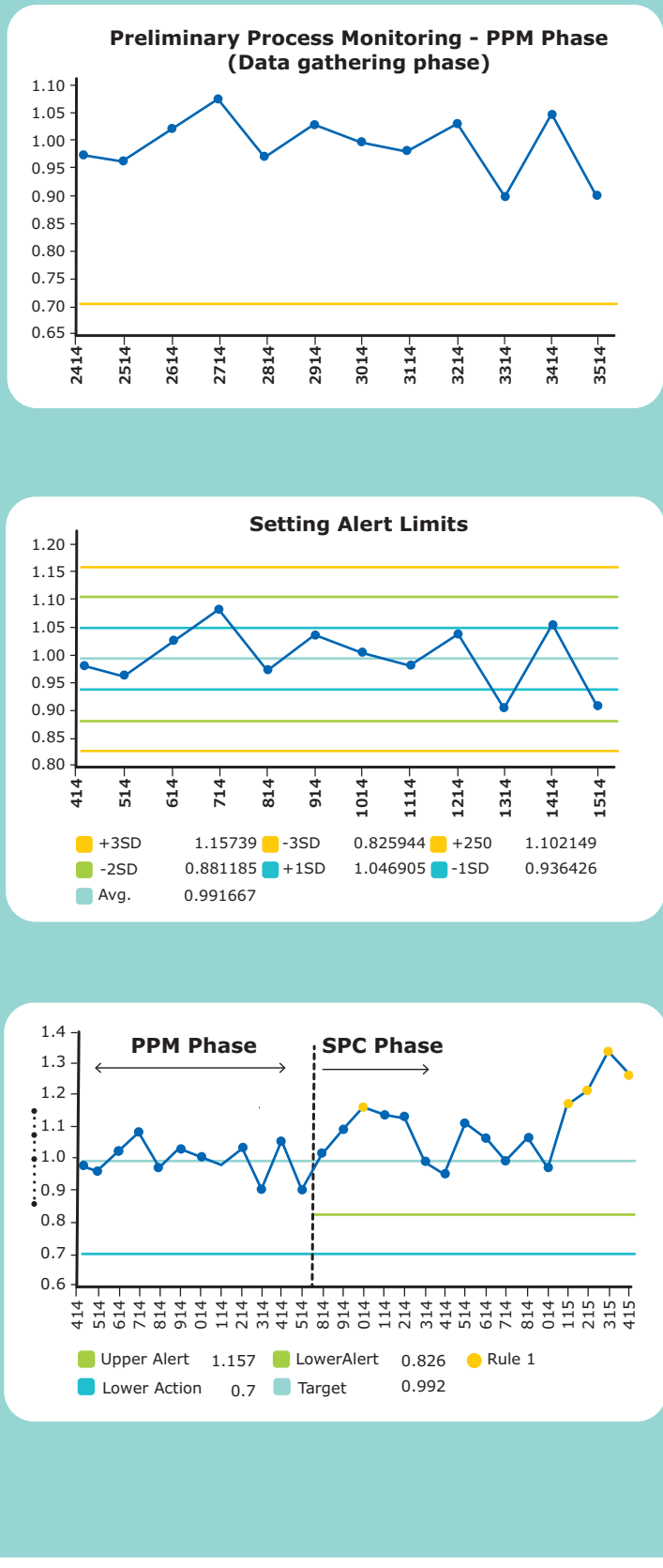


Figure 4. Process Monitoring Phases

Trending Rules

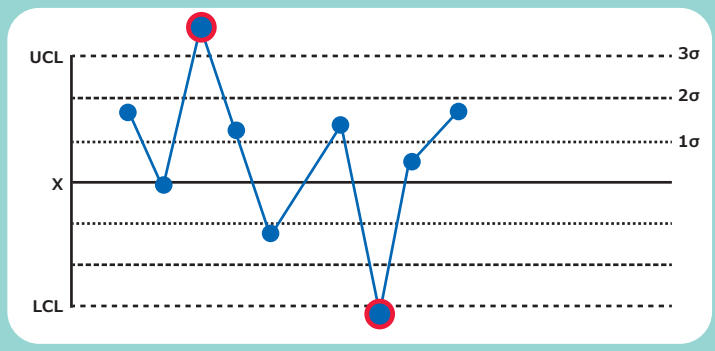
Some form of Nelson (or Western Electric) rules should be established and used for out-of-trend detection as a method to determine if some process parameters are out of control.

Examples of Rule Definitions

The first four Nelson rules that can be used to trend parameters and detect out-of-control batches are described in Figure 5 below.

Rule 1.

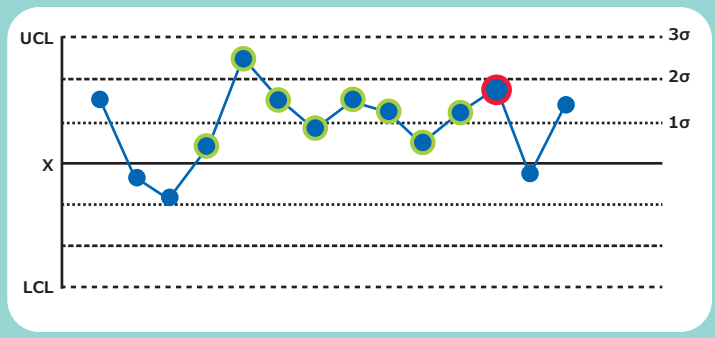
One point is more than 3 standard deviations (UCL, LCL) from the mean.



One sample (two shown in this case) is grossly out of control.

Rule 2.

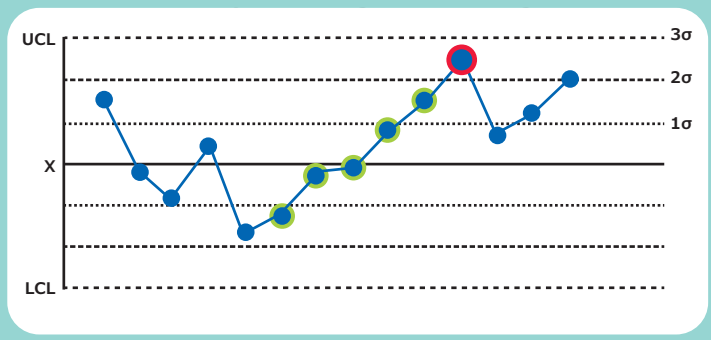
Nine (or more) points in a row are the same side of the mean.



Some prolonged bias exists.

Rule 3.

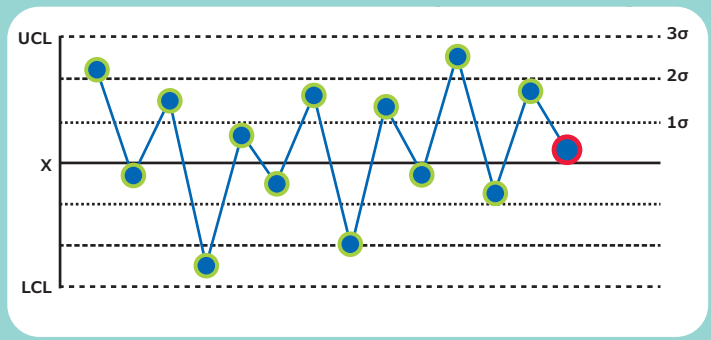
Six (or more) points in a row are continually increasing (or decreasing).



A trend exists.

Rule 4.

Fourteen (or more) points in a row alternate in direction, increasing then decreasing.

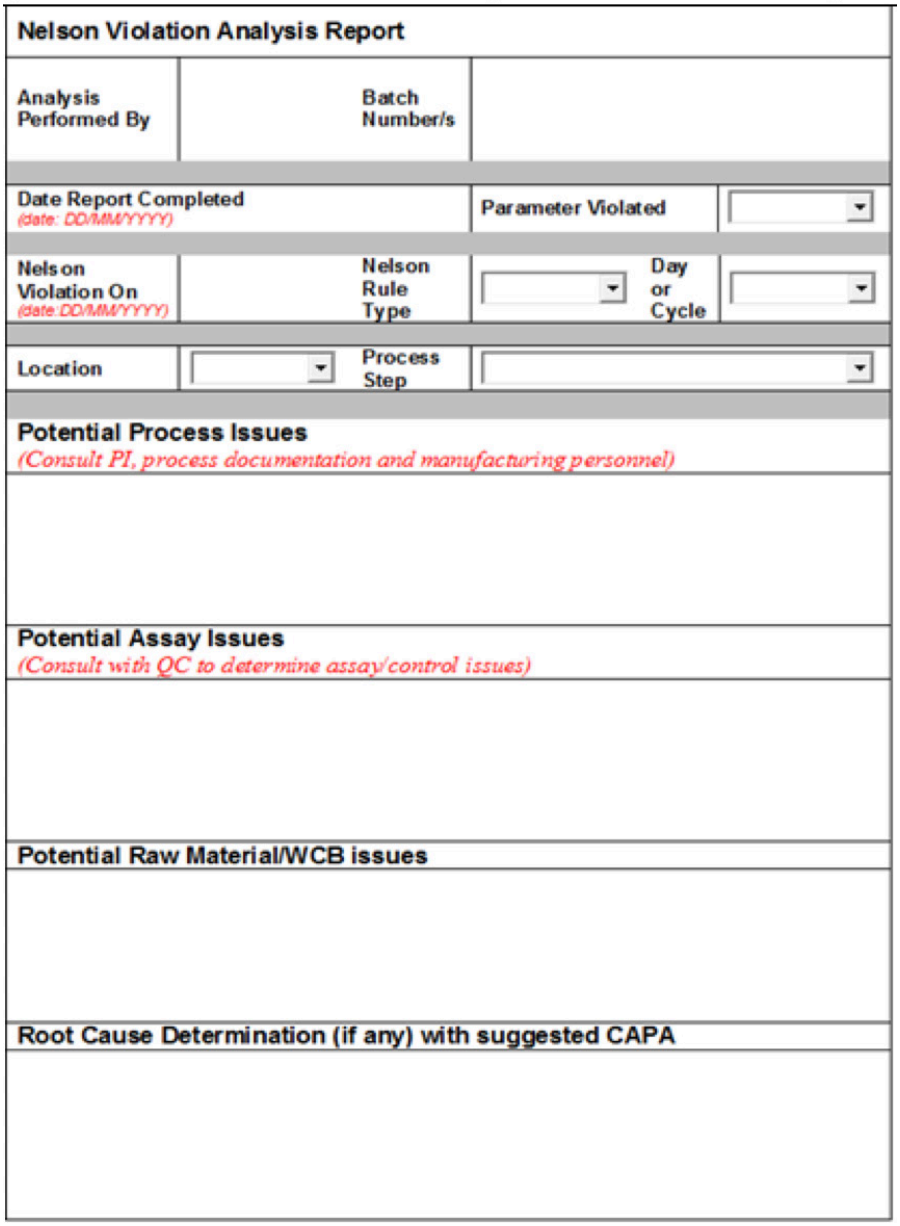


This much oscillation is beyond noise. This is directional, and the position of the mean and size of the standard deviation do not affect this rule.

Figure 5. Nelson Rules

Rule Violation Investigation Approach

A batch violating any of the four trending rules should be properly investigated and closed with appropriate corrective and preventative actions (CAPA). Since these investigations do not impact the disposition of a batch, it will not follow the rigor of a formal quality management system; however, the process monitoring group should be responsible for tracking all such investigations related to trend rule violations. Furthermore, subject matter experts (SMEs) should be consulted appropriately with a formal feedback form. These feedback forms should be documented within the process monitoring group and summarized (and attached as appendix) in the periodic **process monitoring summary reports**. An example of the investigation form that can be used by SMEs is shown in Figure 6.



Nelson Violation Analysis Report

Analysis Performed By		Batch Number/s	
Date Report Completed (date: DD/MM/YYYY)		Parameter Violated	
Nelson Violation On (date:DD/MM/YYYY)		Nelson Rule Type	Day or Cycle
Location		Process Step	

Potential Process Issues
(Consult PI, process documentation and manufacturing personnel)

Potential Assay Issues
(Consult with QC to determine assay/control issues)

Potential Raw Material/WCB issues

Root Cause Determination (if any) with suggested CAPA

Figure 6. Feedback Form

Documentation and Reporting

Routine monitoring status should be periodically presented to key process stakeholders within the organization and reports published to document the process knowledge as explained in the following sections.

In-process Control and Monitoring (IPCM) Document

An IPCM document should be prepared for each commercial process for each manufacturing location. The document should list all performance process parameters (CPP, KPP and MP) that will be routinely monitored with appropriate justification. This document should also list process limits (specification, action and control limits) for all monitored parameters along with suggestions on statistical treatment of each parameter based on distribution of data. This document should be periodically revisited for any additions or removals of a monitored parameter, changes in process limits, or statistical treatment. All changes to the monitoring plan should be added as addendums or annexures. It is suggested to have a limit change log for each monitored parameter in this report. This document should be version controlled. At a minimum, the IPCM document should contain the following sections:

- Process flow chart
- Table providing a list of process monitoring parameters (CPP, KPP, and MP). The table will include the following:
  - Justification for including the parameter in the monitoring program and reason for monitoring
  - If any KPP or CPP is excluded from the monitoring program, a justification as to why should be recorded
  - Report ID of the reference report where justification of why a parameter is a CPP or KPP is given
- Table providing Specification Limits for CPP and Action Limits for CPP and KPP which should also include:
  - Observed distribution of model data set for limits calculation
  - Report ID of reference report which where the source of specification and action limits is given
- Table providing Control Limits (UCL, LCL, and CL) of all monitored parameters (CPP, KPP and MP)
- Change log of all control limits when the limits are revised referencing the report ID of investigation that lead to change of limits
- Distribution Q-Q plots of all monitored (CPP, KPP, MP) parameter (Annexure)

Periodic Presentation of Process Trends

All monitored parameters should be routinely trended on a weekly basis for each commercial process with respect to each processing location (manufacturing site or manufacturing suite). When commercial operations are ongoing, key findings (alerts, etc.) from routine monitoring should be presented to key stakeholders at a regular frequency (preferably every 2 to 3 weeks; not exceeding 4 to 6 weeks). Key stakeholders should include people from manufacturing, process development or manufacturing sciences, quality control and quality assurance.

Quarterly Process Summary Reports

Process Summary Reports should be published every quarter for each commercial process per manufacturing location. At a minimum, the summary report should contain the following sections:

- List of batches produced
- High Impact Process Deviations
  - Root cause (if identified)
  - CAPA (if identified)
  - Impact on monitoring (include/exclude from future monitoring statistics)
- Trend Rule Violations
  - Nelson 1 violations
  - Nelson 2,3 and 4 violations
- Assessment of Process Capability
- CAPA
  - Trend CAPAs identified
  - Status of CAPA for last quarter report
- Duly filled Nelson assessment forms for each violated parameter (Annexure)
- Process Trend Charts (Annexure)

Site Trend Violation and CAPA Report (Quarterly)

Overall operations trend violations and CAPA reports should be prepared at periodic intervals (quarterly recommended) for all products and processes for all manufacturing locations. The reports should highlight the differences or similarities of violations across products, processes and locations.

summary

CPV Flow Chart

As described in earlier sections, the entire CPV process flow is 11 steps (Figure 7).

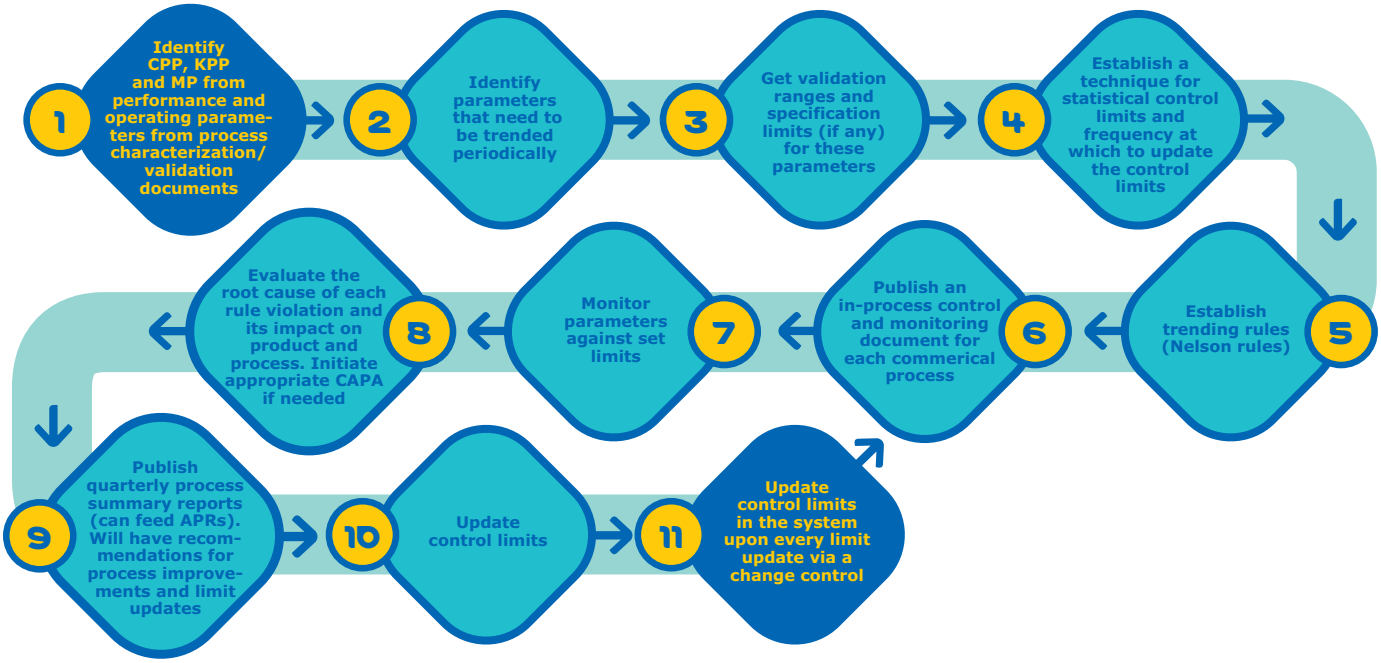


Figure 7. The entire CPV process flow

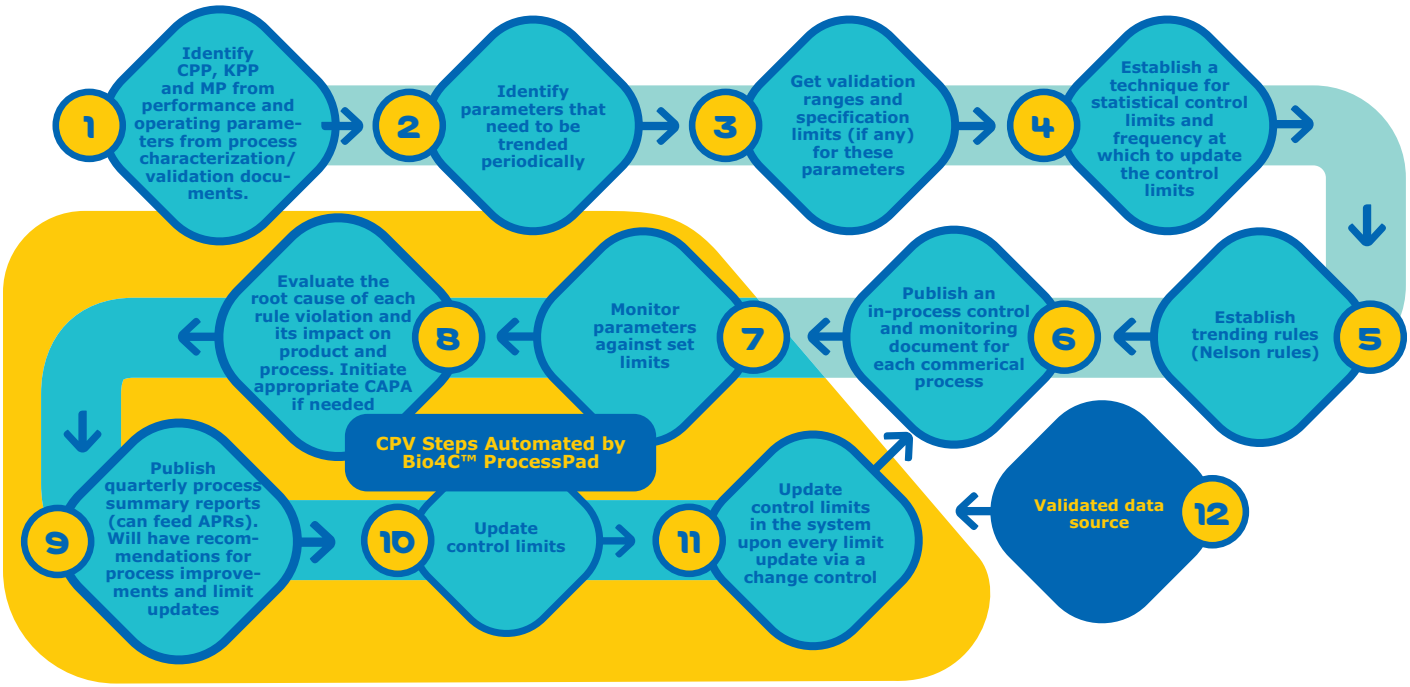


Figure 8. CPV steps automated with Bio4C™ ProcessPad

Bio4C™ ProcessPad CPV Platform

Bio4C™ ProcessPad is a data visualization, analytics, and process monitoring platform that enables bioprocess lifecycle management, reporting, investigations, and continued process verification. It stores the batch processing and analytical testing data in a validated state so that the data can be easily available for process troubleshooting and process benchmarking operations. It also aids organizations in their compliance efforts by meeting all the applicable requirements of 21 CFR Part 11.

Why is Bio4C™ ProcessPad a Comprehensive CPV Solution?

Continued Process Verification is the lengthiest and most data heavy phase of process validation. It requires continuous monitoring of processes against defined limits (specification, action and statistical control limits) throughout the commercial life of a product. Bio4C™ ProcessPad is a comprehensive CPV solution which automates many of the business processes in a CPV program (Figure 9).

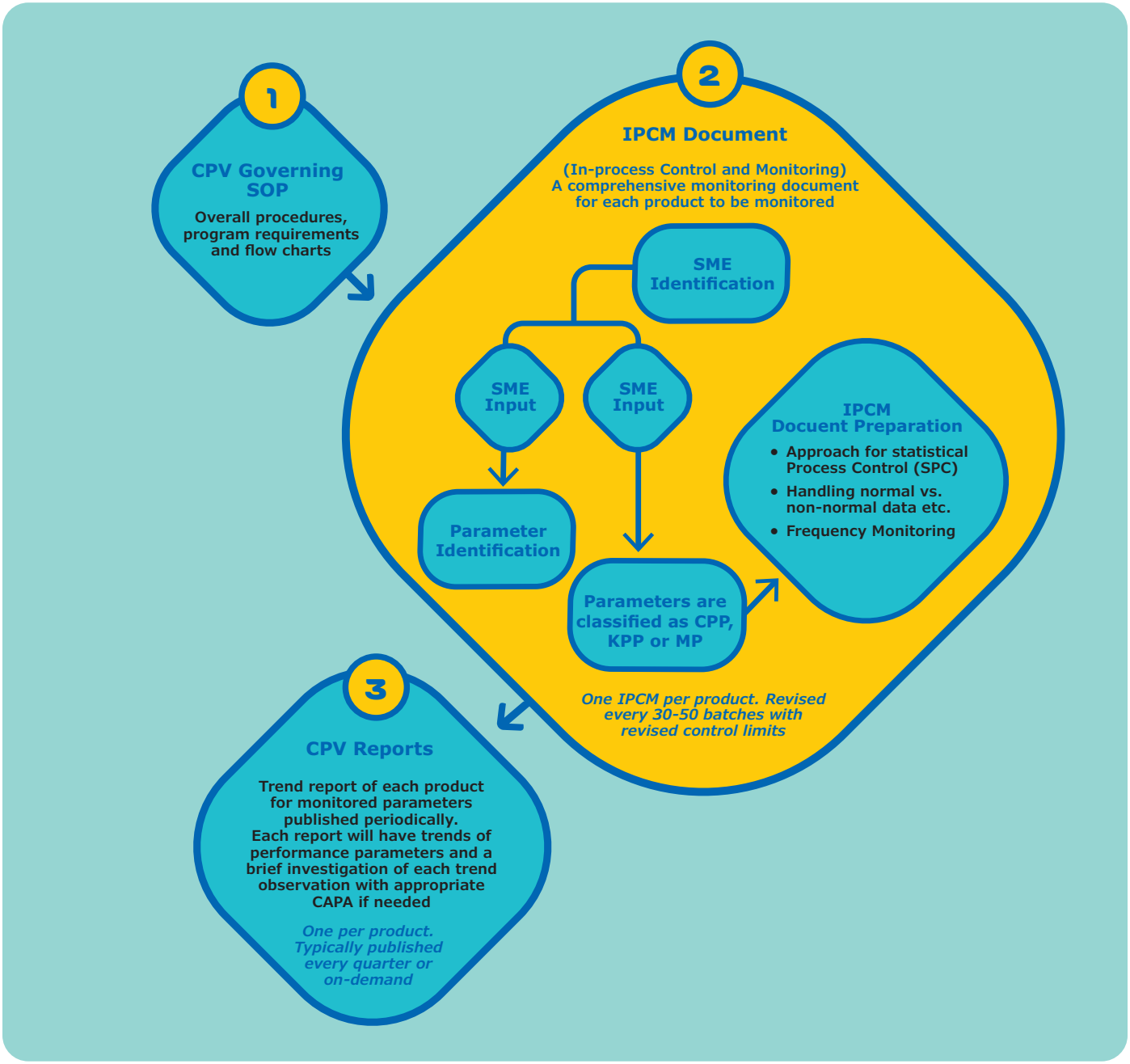


Figure 9. Documentation required to roll-out a CPV program and its organization.

FDA Expectations for CPV

An Ongoing Program for Collecting and Analyzing Product and Process Data that Relate to Product Quality

- Procedures for data **collection** and **trending**
- Data collected should verify the quality attributes
- **Intra-batch** and **inter-batch** variation
- Data should be collected to evaluate process **stability** and **capability**
- Data should be **statistically trended**
- It is recommended that a statistician or person with adequate statistical training develop the data collection plans and methods for analysis

Must Have a System for Detecting Unplanned Departures from the Process

- Evaluate the **performance** of the process
- **Identify problems**
- Determine if corrective action is necessary
- Anticipate and prevent problems to ensure control

Key Differentiators of Bio4C™ ProcessPad

Validated Data Source

Bio4C™ ProcessPad is a validated data source. All the data entered in Bio4C™ ProcessPad goes through two layers of verification to ensure that data entered is accurate and reliable. Bio4C™ ProcessPad has stringent access level control. For example, a user uploading data does not have permissions to approve the data; similarly, an approver does not have permissions to upload data. Bio4C™ ProcessPad also has audit trail which captures every action performed by all users.

Plug-and-Play Monitoring

Bio4C™ ProcessPad was designed from the ground up for process monitoring. The following features make Bio4C™ ProcessPad an ideal tool to monitor your processes:

1. Create and schedule creation of control charts
2. Version control statistical limits revisions and log historical contextual process knowledge
3. Storage of historical limits and displaying in a single chart limits revisions and process performance within each limit revision
4. Automatic calculation of statistical trend rule violation
5. Automatic capability analysis (Cpk and Ppk calculation)
6. Prediction of data distribution (normal or non-normal data distribution)
7. Perform linear correlations with parameters across process steps

Bio4C™ ProcessPad offers out-of-the-box data visualizations and analytics than can accelerate investigations and root.

Report Generation (CPV/APQR)

CPV reporting is a tedious task. It involves collection of data from all the batches executed in that time frame and trending them with statistical control limits, calculation of process capabilities (Cpk and Ppk) and sighting the statistical trend rule violation.

Standardized campaign (CPV) reports can be prepared in Bio4C™ ProcessPad. Report templates are prepared by selecting the desired parameters from all the process stages into a trending template. This template can then be scheduled for automatic periodic report generation.

Salient Features of Bio4C™ ProcessPad in Comparison to Traditional Software

There is numerous software available on the market which claims to do CPV reporting but none of them perform the combined task. For example, Microsoft® Excel can be used to make control charts with defined control limits, but it is extremely difficult to define (and validate) trend rules and calculate process capability within the charts. Similarly, other desktop spreadsheet-based advanced statistical software packages in the market although good spreadsheet software with the ability to trend charts preparation and perform process capability calculations, they lack any ability to validate archived data, which breaks the very first rule of CPV i.e. data sources must be validated.

Bio4C™ ProcessPad has an embedded database with a workflow to capture and store batch record or experiment execution data in a 21 CFR Part 11 compliant manner. All data entered into Bio4C™ ProcessPad is part of an audit trail. This is lacking in traditional software which does not have any process of capturing and storing in-process parameters. As Bio4C™ ProcessPad stores the data in a database, this data can be made available to the end user on demand. As far as competing software are concerned, they are standalone desktop applications without any proper data capture or data storage mechanism. These traditional software applications need to be fed data from an externally aggregated spreadsheet whenever performing analysis.

Bio4C™ ProcessPad has an evolved system to perform continued process verification with automated reports on CTQs and CPPs. It supplies out-of-the- box trend analysis with trend violation detection using Nelson or Western Electric rules. Furthermore, it has an advanced system of recording control limits and their revision history to give insights on evolving process capabilities which is required for any MSAT or process support R&D team.

Bio4C™ ProcessPad has contextual connection between process steps (unit operations) giving users easy access to parameter correlations between parameters from across process steps with advanced data visualization technologies. Investigators can easily generate complete lot genealogies on demand. Other commercially available machine analytics software applications are primarily focused on upstream process data with monitoring via MVDA techniques and ignoring important offline/at-line data analysis and trending. There are no capabilities in these software where users can find downstream process data monitoring or CTQ/CPP management and monitoring. Bio4C™ ProcessPad's golden tunnel dashboards for machine data provides a simple and extremely easy way to monitor live processes in historical context.

Bio4C™ ProcessPad is the only truly browser-based software available in the market for CPV. Being 100% browser based and built using the latest web technologies (which are inherently collaborative), Bio4C™ ProcessPad is well suited for collaboration, scale, and performance. Offered as a site license for unlimited users makes it economical and easily adopted by various stakeholders in the organizations. Applications can be accessed via a web browser within the company IT network. Other software in the market are licensed per user and requires organizations to install software on each local PC making it expensive and difficult to manage/scale.

Other competing software applications have long learning curves and are difficult to operate and master. Bio4C™ ProcessPad user interface is extremely simple with minimal training requirements. Bio4C™ ProcessPad can be deployed within weeks at a site as compared to months in the case of other software.

The whole architecture of Bio4C™ ProcessPad has been designed and purpose-built for pharmaceutical and biopharmaceutical organizations making it easily adoptable within these organizations at all user levels. On the other hand, other software is focused on advanced analytics which only expert data scientist in the organization can understand and use to the full extent. Bio4C™ ProcessPad is a tool for all levels of expertise rather than few statisticians.

For additional information
please visit **EMDMillipore.com/Bio4CProcessPad**

To place an order or receive technical assistance
please visit **EMDMillipore.com/contactPS**
or email **ProcessPadSupport@EMDGroup.com**

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