



PI CPV

Digitized Continued Process Verification for Pharmaceutical Companies



The CPV Challenge

Continued Process Verification (CPV) monitors critical process parameters throughout the product lifecycle to ensure manufacturing processes remain in control. It identifies trends, anomalies, and variability to maintain compliance with regulatory standards.

However, organizations struggle with managing large datasets and adhering to structured guidelines consistently.



Introducing PI CPV

A state-of-the-art automation platform designed to digitize the entire CPV lifecycle

Statistical Analytics

Advanced data analysis capabilities for process monitoring

Seamless Integration

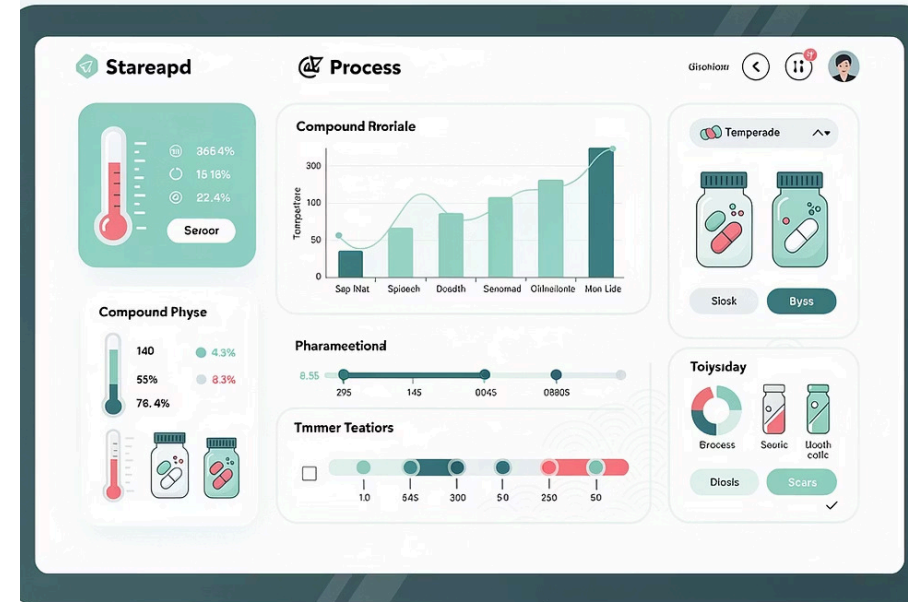
Connect with LIMS, SAP, TrackWise, and other systems

Customizable Reporting

Flexible templates tailored to your needs

Regulatory Compliance

Built-in adherence to global standards



Structured Workflow & Collaboration

01

Development

Create CPV protocols with built-in e-signature support

02

Review

Capture comments for transparency across teams

03

Approval

Track status visibility and ensure accuracy

04

Completion

Achieve timely collaboration and compliance



Centralized Data Repository

Unified Integration

PI CPV integrates with key systems to unify data from multiple sources:

- LIMS
- SAP
- TrackWise
- EDMS

Real-Time Visibility

Centralized access enables:

- Batch information and materials tracking
- Analytical methods and process data
- Process deviations and recalls
- Investigations and corrective actions



The approved Protocol and CPV reports Calendar is listed below. For this Calendar, alterations can be made using the Calendar Addendum features.

CPV Calendar | Version: 1.0
 Review Status: Approved Year at End of CPV: 2023
 Countries: EU,India,ROW,US Product Type: Non-Sterile

Buttons: Open/Create Calendar Addendum, Export Calendar, Calendar as site

Click the arrow to show/hide the full instructions for this screen.

Sl N.	Product Name	Effective Protocol number	Effective Protocol Date	Re-evaluation start date for 2023	Re-evaluation Due Date	Re-evaluation Status	Revision Required ?	NextStep	Assigned Users	Protocol Details
1	Product A Tablet 10 mg	CPV Product A 10-2021-02	03-15-2021	03-15-2023	05-14-2023	Completed	No	View Latest Protocol	User 1	
2	Product D	CPV Product D 100-2019-02	06-21-2019	06-21-2023	08-20-2023	Completed	Yes	Create Revised Protocol	User 1	
3	Product T Capsule 0.25mg	CPV Product A 0.25-2023-01	07-05-2022	07-05-2023	09-03-2023	Completed	Yes	View Latest Protocol	User 1	View Re-evaluation Details
4	Product C Tablet 1.2 gm	CPV Product C 1.2-2021-04	08-19-2019	08-19-2023	10-18-2023	Not Initiated		Re-evaluate Protocol	User 10	
5	Product BA (DL) Pellets							Create new Protocol	User 11	

FEATURE 3

Smart Scheduling & Tracking

1

Annual Planning

Schedule CPV protocol creation and re-evaluations

2

Periodic Reports

Organize report schedules and addendum creation

3

Management Tracking

Generate reports to monitor CPV statuses effectively

4

Notifications

Automated emails inform stakeholders of deadlines

Export options to Word or PDF formats simplify audits and archiving.

FEATURE 4

Automated CPV Protocol Management



Data Collection

Gather CPPs and CQAs from manufacturing processes



Data Analysis

Establish limits using SPC charts and trend analysis



Re-evaluation

Periodic protocol reviews maintain control standards

This structured workflow enables efficient protocol review and execution while maintaining compliance standards.

Click the arrow to show/hide the full instructions for this screen

Product T Capsule 0.25mg (US) | CPV Product A 0.25 2022 01_01
 Effective Protocol Number: CPV Product A 0.25 2022 01
 Review Period: 01-06-2022 To 31-12-2022 Review Status: Draft

Specify Criteria | Export CPV Report | More Options | Save

Export List | Add Summary Tab | Review Comments | Tables & Ops | Check In | ✓ Checked out from 28-11-2022 01:21

APPEND

Total OOS(s) : 2 | Closed : 2 | Open : 0

Batch No.	OOS ID #	Product Name	Batch No./Stage	Attribute for Which OOS is received	Spec Limit	Result	State of OOS/Open/Cl...
1	PKA 654378	Product T Capsule 0.25mg (US)	Material Name : Product T 0.25mg (K) Capsule Material Code : 1121493 Batch No : Batch 12 Stage : Finished Good	ASSAY		Refer detail description	Closed - Done

Investigational Outcome(Root cause)

Root Cause Summary:
 In the laboratory investigation, no laboratory error was identified for out of specification results.
Investigation Conclusion:Based on the laboratory investigation, raw data checking and discussion with analyst, *Analysis was performed by a trained and was found well within acceptance criteria. Hence, error due to standard preparation was unlikely. *Preliminary investigation performed, and no laboratory interaction with analyst and bench top investigation, however to find out any error associated with analyst and/or instrument malfunctioning initial report SSSU/SSDV/WOL/SSDV/WLD and ES found in alignment with initial analysis result for both the content of both the batches. *Critical hyperbolic performance *Additionally, verified the standard response factor and found comparable with previous trend. *No laboratory error identified for initial OOS result base...

FEATURE 5

Streamlined CPV Report Generation



Configurable Templates

Support for single or multiple product strengths and markets



Flexible Import

Import standardized Excel files or enter data manually



Data Validation

Configurable rules ensure accuracy and consistency



Export Options

Generate Word or PDF formats for audits and archiving

🔗 FEATURE 7

AI-Augmented Summaries



Automated Intelligence

Generative AI creates summaries and recommendations based on CPV data



User Control

Override AI-generated content as desired to maintain accuracy

Data Security & Regulatory Compliance



Audit Trails

Secure tracking of all changes and approvals for complete transparency



E-Signatures

Embedded digital signatures ensure data integrity and authenticity



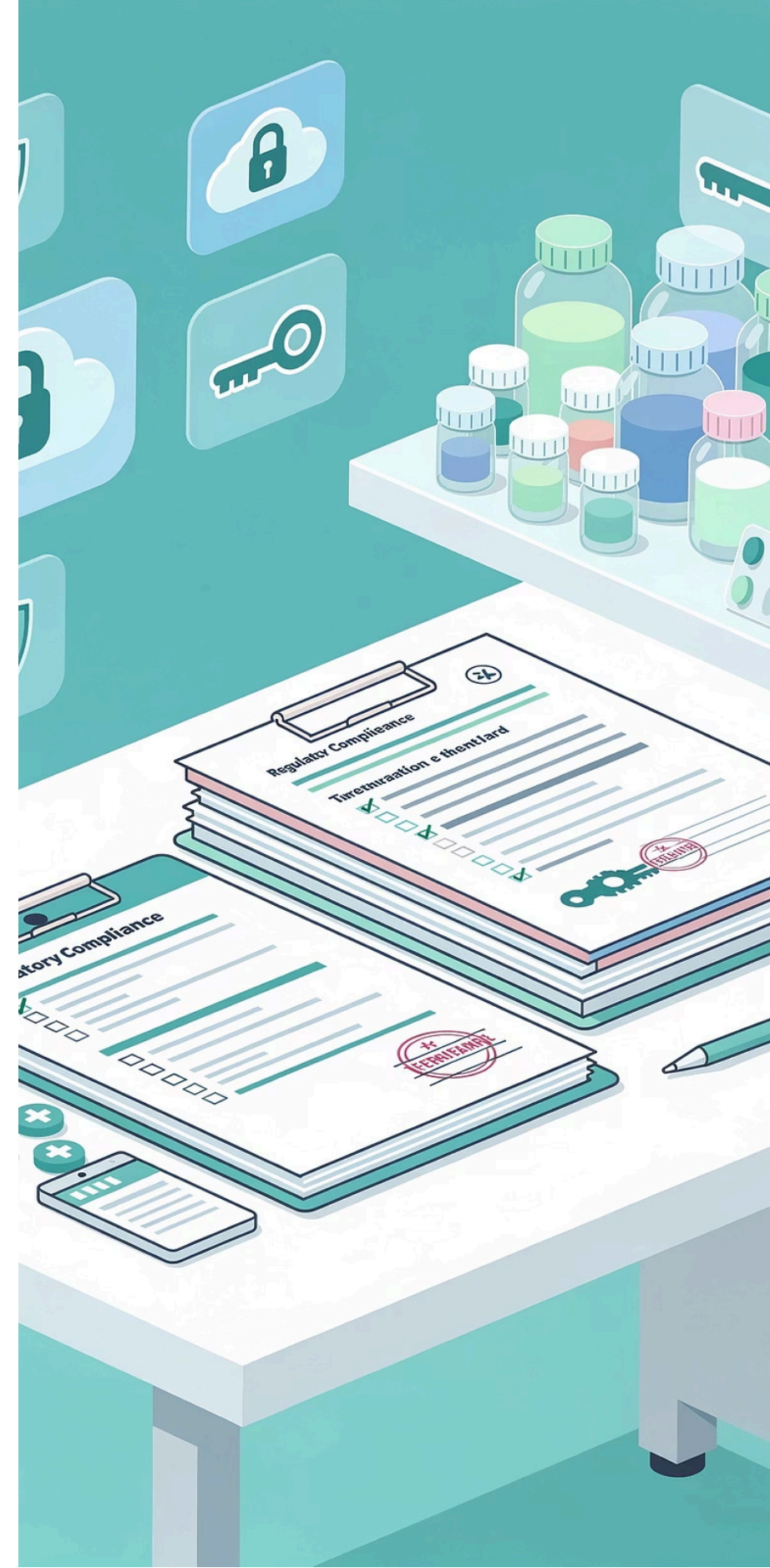
Global Standards

Compliant with CGMP, 21 CFR Part 11, and EU Annex 11 regulations



Inspection Ready

Exportable change histories prepared for regulatory inspections



The PI CPV Advantage

Transform your CPV process with complete digitization



Minimize Manual Effort

Reduce errors through automation and streamlined workflows



Enhance Capability

Improve process and product quality with advanced analytics



Regulatory Readiness

Maintain compliance with embedded regulatory features

